

US3202191 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:41:09

All time stamps listed in this document are displayed in GMT

US3202191

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 15:35:11

Generated On: 09 Jun 2021 15:41:09

Participant ID

US3202191

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

US3202191

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Date of Birth (MMM yyyy)	(b) (6) 1943
Age	77
Age Units	YEARS
Age (Derived)	77
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) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Date of Informed Consent (<i>dd MMM yyyy</i>)	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3202191

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN SEP 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)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Condition	EPISODIC EDEMA BILATERAL LEGS
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 (6)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Condition	HIGH CHOLESTEROL
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 (7)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Condition	OSTEOARTHRITIS IN SHOULDERS BILATERAL
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 1950
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 1950
Start Year (derived)	1950
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Condition	ANOSMIA
Start date (dd MMM yyyy)	UN UNK 1943
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1943
Start Year (derived)	1943
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Condition	AXONAL NEUROPATHY
Start date (dd MMM yyyy)	UN JUN 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)	JUN 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) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Condition	OSTEOARTHRITIS RIGHT ANKLE
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Condition	DEGENERATIVE DISC DISEASE LUMBAR SPINE
Start date (dd MMM yyyy)	UN UNK 1983
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 1983
Start Year (derived)	1983
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Condition	CEREBRAL VASCULAR ACCIDENT
Start date (dd MMM yyyy)	UN JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Condition	GAIT DISTURBANCE
Start date (dd MMM yyyy)	UN JUN 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)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Condition	SUBACUTE CHRONIC INFARCTION IN LEFT POSTERIOR LOBE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Condition	CHRONIC INFARCTION IN LEFT CEREBELLAR HEMISPHERE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:40 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:40
Height (<i>xxx.x</i>)	183.0 cm
Weight (<i>xxx.x</i>)	150.0 kg
BMI (<i>xxx.x</i>)	44.79083 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) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:11:06

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

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

Visit date (dd MMM yyyy)	14 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

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

What was the participant's randomization number? 186327

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

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) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

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)	14 AUG 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:40
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

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)	14 AUG 2020
Time of assessment (00:00-23:59)	14:06 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 14:06
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 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) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

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) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 13:19 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 13:19

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) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 AUG 2020
Collection time (00:00-23:59)	12:57 (24 HR)
Collection date and time (derived)	14 AUG 2020 12:57

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:55	14 AUG 2020 12:55
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

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: 09 Jun 2021 15:41:09

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 14:12

PC Open Date & Time

14 AUG 2020 13:39

PC Close Date & Time

14 AUG 2020 16:09

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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 97.5 °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	14 AUG 2020 17:10
PC Open Date & Time	14 AUG 2020 17:04
PC Close Date & Time	15 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

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	98.0 °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	True
PC Time Stamp	15 AUG 2020 12:16
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

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):

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

True

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

16 AUG 2020 12:10

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

True

PC Time Stamp

17 AUG 2020 12:30

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

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.

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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	97.7 °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 True

PC Time Stamp 18 AUG 2020 12:08

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

19 AUG 2020 12:19

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

True

PC Time Stamp

20 AUG 2020 14:36

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:09

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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

21 AUG 2020 12:02

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:09

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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

True

PC Time Stamp

22 AUG 2020 13:10

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:09

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 <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 True

PC Time Stamp 23 AUG 2020 12:02

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:41:09

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.

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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	97.6 °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	True
PC Time Stamp	24 AUG 2020 12:02
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 15:41:09

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.

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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

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 15:41:09

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.

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

26 AUG 2020 13:04

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 15:41:09

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.

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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	97.5 °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
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To PREVENT pain or fever from occurring	True
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PC Time Stamp	27 AUG 2020 13:01
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PC Open Date & Time	27 AUG 2020 12:00
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PC Close Date & Time	28 AUG 2020 11:59
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US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 15:41:09

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	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	True
PC Time Stamp	28 AUG 2020 13:16
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 15:41:09

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.

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	98.0 °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	29 AUG 2020 12:04
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 15:41:09

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 ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

30 AUG 2020 12:50

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 15:41:09

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.

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	97.7 °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
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To PREVENT pain or fever from occurring	True
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PC Time Stamp	31 AUG 2020 12:13
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PC Open Date & Time	31 AUG 2020 12:00
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PC Close Date & Time	01 SEP 2020 11:59
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US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 15:41:09

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °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	True
PC Time Stamp	01 SEP 2020 16:01
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 15:41:09

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °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	True
PC Time Stamp	02 SEP 2020 12:05
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 15:41:09

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	97.5 °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	True
PC Time Stamp	03 SEP 2020 12:38
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 15:41:09

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	97.5 °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	True
PC Time Stamp	04 SEP 2020 12:01
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 15:41:09

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.

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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	97.5 °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	True
PC Time Stamp	05 SEP 2020 12:01
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 15:41:09

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.

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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 True

PC Time Stamp 06 SEP 2020 12:03

PC Open Date & Time 06 SEP 2020 12:00

PC Close Date & Time 07 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 25

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.

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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	97.5 °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	07 SEP 2020 12:12
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 26

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

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

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

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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	97.5 °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	True
PC Time Stamp	08 SEP 2020 13:01
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 27

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 13:22

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 14:13

PC Open Date & Time

14 AUG 2020 13:39

PC Close Date & Time

14 AUG 2020 16:09

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 17:12

PC Open Date & Time

14 AUG 2020 17:04

PC Close Date & Time

15 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 12:17

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:11

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 12:31

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 12:10

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 12:19

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 14:36

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 14:15
PC Open Date & Time	14 AUG 2020 13:39
PC Close Date & Time	14 AUG 2020 16:09

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 17:13
PC Open Date & Time	14 AUG 2020 17:04
PC Close Date & Time	15 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

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 ☒

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☒

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 12:32
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

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 ☒

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 14:37
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:09

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

21 AUG 2020 12:03

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:09

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 22 AUG 2020 13:10

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 10

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

23 AUG 2020 12:02

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 11

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

24 AUG 2020 12:03

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 12

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

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 13

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

26 AUG 2020 13:05

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 14

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

27 AUG 2020 13:01

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 15

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

28 AUG 2020 13:16

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 16

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

29 AUG 2020 12:04

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 17

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

30 AUG 2020 12:50

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 18

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

31 AUG 2020 12:13

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 19

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

01 SEP 2020 16:02

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 20

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

02 SEP 2020 12:05

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 21

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

03 SEP 2020 12:38

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 22

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

04 SEP 2020 12:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 23

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

05 SEP 2020 12:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 24

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

06 SEP 2020 12:03

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 25

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

07 SEP 2020 12:12

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 26

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

08 SEP 2020 13:01

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 27

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 13:22

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 28

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 19:02

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 29

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

11 SEP 2020 12:31

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 30

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

12 SEP 2020 12:40

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(31)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 31

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

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(32)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 32

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

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 21 AUG 2020 12:03

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 22 AUG 2020 13:11

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 23 AUG 2020 12:02

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 24 AUG 2020 12:03

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 26 AUG 2020 13:05

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

27 AUG 2020 13:01

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 28 AUG 2020 13:16

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

29 AUG 2020 12:04

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 30 AUG 2020 12:51

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 31 AUG 2020 12:13

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 01 SEP 2020 16:02

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

02 SEP 2020 12:05

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 03 SEP 2020 12:39

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

04 SEP 2020 12:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 05 SEP 2020 12:01

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

06 SEP 2020 12:03

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

07 SEP 2020 12:12

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 26

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 08 SEP 2020 13:01

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 27

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

09 SEP 2020 13:22

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 28

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

10 SEP 2020 19:02

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 29

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 11 SEP 2020 12:31

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 30

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp

12 SEP 2020 12:40

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(31)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 31

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(32)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 32

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 21 AUG 2020 12:03

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 22 AUG 2020 13:11

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 23 AUG 2020 12:02

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 24 AUG 2020 12:03

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 26 AUG 2020 13:05

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 27 AUG 2020 13:01

PC Open Date & Time 27 AUG 2020 12:00

PC Close Date & Time 28 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 28 AUG 2020 13:16

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 29 AUG 2020 12:04

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 30 AUG 2020 12:51

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 31 AUG 2020 12:13

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 01 SEP 2020 16:02

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

02 SEP 2020 12:06

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 03 SEP 2020 12:39

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 04 SEP 2020 12:02

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 05 SEP 2020 12:01

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

06 SEP 2020 12:04

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 25

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

07 SEP 2020 12:12

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 26

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 08 SEP 2020 13:01

PC Open Date & Time 08 SEP 2020 12:00

PC Close Date & Time 09 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 27

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp

09 SEP 2020 13:22

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 28

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 10 SEP 2020 19:02

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 29

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 11 SEP 2020 12:31

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 30

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 12 SEP 2020 12:40

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 31

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 32

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:09

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	21 AUG 2020 12:04
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:09

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	22 AUG 2020 13:11
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:09

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	23 AUG 2020 12:03
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 11
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	24 AUG 2020 12:03
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 12
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	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 13
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	26 AUG 2020 13:05
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:41:09

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	27 AUG 2020 13:02
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:41:09

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	28 AUG 2020 13:16
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:41:09

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	29 AUG 2020 12:05
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:41:09

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	30 AUG 2020 12:51
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 15:41:09

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	31 AUG 2020 12:14
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 19
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	01 SEP 2020 16:02
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 15:41:09

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	02 SEP 2020 12:06
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 15:41:09

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	03 SEP 2020 12:39
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 15:41:09

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	04 SEP 2020 12:02
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 23

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

No ☒

Yes ☐

PC Time stamp

05 SEP 2020 12:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 15:41:09

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	06 SEP 2020 12:04
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 25
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	07 SEP 2020 12:13
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 26
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	08 SEP 2020 13:01
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 27

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

No ☒

Yes ☐

PC Time stamp

09 SEP 2020 13:22

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 28
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 19:02
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 29
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 SEP 2020 12:31
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 30
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	12 SEP 2020 12:40
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 31
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	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 32
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	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3202191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3202191

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202191

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202191

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:11:07

Generated On: 09 Jun 2021 15:41:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:11:07

Generated On: 09 Jun 2021 15:41:09

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)	24 SEP 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 09:10
Temperature (xxx.x)	97.4 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)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:11:07

Generated On: 09 Jun 2021 15:41:09

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 10:45
Temperature (xxx.x)	39.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3202191

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:11:07

Generated On: 09 Jun 2021 15:41:09

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.

US3202191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 10:06 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 10:06

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

What was the frequency of the study treatment dosing? ONCE

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

US3202191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:11:07

Generated On: 09 Jun 2021 15:41:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 SEP 2020

Collection time (00:00-23:59)

09:26 (24 HR)

Collection date and time (derived)

24 SEP 2020 09:26

US3202191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:24	24 SEP 2020 09:24
Nasopharyngeal Swab 2	No		

US3202191

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:06

Generated On: 09 Jun 2021 15:41:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 10:46

PC Open Date & Time

24 SEP 2020 10:26

PC Close Date & Time

24 SEP 2020 12:56

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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 97.3 °F

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

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

PC Time Stamp	24 SEP 2020 15:23
PC Open Date & Time	24 SEP 2020 13:51
PC Close Date & Time	25 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 13:39

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 12:01

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 12:08

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

28 SEP 2020 14:26

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

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

29 SEP 2020 12:02

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 13:59

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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

24 SEP 2020 10:48

PC Open Date & Time

24 SEP 2020 10:26

PC Close Date & Time

24 SEP 2020 12:56

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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

24 SEP 2020 15:24

PC Open Date & Time

24 SEP 2020 13:51

PC Close Date & Time

25 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

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

25 SEP 2020 13:39

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

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

26 SEP 2020 12:01

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

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

27 SEP 2020 12:09

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

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

28 SEP 2020 14:27

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

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

29 SEP 2020 12:02

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

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

30 SEP 2020 13:59

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 10:48
PC Open Date & Time	24 SEP 2020 10:26
PC Close Date & Time	24 SEP 2020 12:56

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 15:25
PC Open Date & Time	24 SEP 2020 13:51
PC Close Date & Time	25 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

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 ☒

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 13:40
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

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 ☒

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 12:02
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

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 ☒

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 12:09
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 14:27
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 12:03
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 14:00
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3202191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202191

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3202191

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:01

Generated On: 09 Jun 2021 15:41:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:11:07

Generated On: 09 Jun 2021 15:41:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:11:07

Generated On: 09 Jun 2021 15:41:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 09:55
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202191

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:11:07

Generated On: 09 Jun 2021 15:41:09

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.

US3202191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:11:07

Generated On: 09 Jun 2021 15:41:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

10:01 (24 HR)

Collection date and time (derived)

23 OCT 2020 10:01

US3202191

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:11:07

Generated On: 09 Jun 2021 15:41:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

14 OCT 2020 05:18:05

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 OCT 2020 06:41:39
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	19 NOV 2020 14:29:01
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

22 NOV 2020 08:19:03

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 18:48:01

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 03:59:38

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 152

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

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 06:46:24

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 09:23:48

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 10:04:07

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 06:22:17

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 06:11:57

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 05:57:17

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 07:00:38

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 07:16:08

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

21 MAR 2021 06:42:51

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 07:30:41

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 12:12:29

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 09:14:47

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 06:15:25

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 07:14:23

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 AUG 2021 00:01
Patient Cloud Close Date & Time	19 AUG 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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°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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JAN 2022 00:01
Patient Cloud Close Date & Time	03 FEB 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 FEB 2022 00:01
Patient Cloud Close Date & Time	10 FEB 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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°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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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24 FEB 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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="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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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="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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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="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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

Patient Cloud Open Date & Time	25 SEP 2022 00:01
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Patient Cloud Close Date & Time	29 SEP 2022 23:59
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US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 ☐

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

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

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3202191

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:41:09

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		28 FEB 2021 05:57:34

US3202191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:44:57

Generated On: 09 Jun 2021 15:41:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 NOV 2020

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

Comments LVM
SUB CALLED BACK ON 19 NOV
If Contact Not Made, please provide Comments 2020

US3202191

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:44:57

Generated On: 09 Jun 2021 15:41:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202191

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:35:13

Generated On: 09 Jun 2021 15:41:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202191

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:35:13

Generated On: 09 Jun 2021 15:41:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202191

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:35:13

Generated On: 09 Jun 2021 15:41:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202191

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:35:13

Generated On: 09 Jun 2021 15:41:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202191

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:35:13

Generated On: 09 Jun 2021 15:41:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202191

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:35:13

Generated On: 09 Jun 2021 15:41:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202191

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:35:13

Generated On: 09 Jun 2021 15:41:09

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

Visit date (dd MMM yyyy)	12 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
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US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 15:35:13

Generated On: 09 Jun 2021 15:41:09

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) _____

US3202191

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:35:13

Generated On: 09 Jun 2021 15:41:09

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.

US3202191

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:35:13

Generated On: 09 Jun 2021 15:41:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 MAR 2021
Collection time (00:00-23:59)	10:49 (24 HR)
Collection date and time (derived)	12 MAR 2021 10:49

US3202191

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:35:13

Generated On: 09 Jun 2021 15:41:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202191

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:41:09

Date of Contact	28 APR 2021
Time of Contact	11:00
Date and Time of Contact (derived)	28 APR 2021 11:00
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

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

Date	22 APR 2021
------	-------------

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

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

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

Fatigue	None <input checked="" type="radio"/>
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EAB) (1725)

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US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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

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

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

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

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

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
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Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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

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

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

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

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

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

Date	23 APR 2021
------	-------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

Fatigue	None <input checked="" type="radio"/>
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Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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

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

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

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

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

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None <input checked="" type="radio"/>	
	Mild <input type="radio"/>	
	Moderate <input type="radio"/>	
	Severe <input type="radio"/>	
	Not Done <input type="radio"/>	
Cough	None <input checked="" type="radio"/>	
	Mild <input type="radio"/>	
	Moderate <input type="radio"/>	
	Severe <input type="radio"/>	
	Not Done <input type="radio"/>	
Shortness of Breath	None <input checked="" type="radio"/>	
	Mild <input type="radio"/>	
	Moderate <input type="radio"/>	
	Severe <input type="radio"/>	
	Not Done <input type="radio"/>	
Difficulty Breathing	None <input checked="" type="radio"/>	
	Mild <input type="radio"/>	
	Moderate <input type="radio"/>	
	Severe <input type="radio"/>	
	Not Done <input type="radio"/>	
Fatigue	None <input checked="" type="radio"/>	
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Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

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

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

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

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Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 APR 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None <input checked="" type="radio"/>	
	Mild <input type="radio"/>	
	Moderate <input type="radio"/>	
	Severe <input type="radio"/>	
	Not Done <input type="radio"/>	
Cough	None <input checked="" type="radio"/>	
	Mild <input type="radio"/>	
	Moderate <input type="radio"/>	
	Severe <input type="radio"/>	
	Not Done <input type="radio"/>	
Shortness of Breath	None <input checked="" type="radio"/>	
	Mild <input type="radio"/>	
	Moderate <input type="radio"/>	
	Severe <input type="radio"/>	
	Not Done <input type="radio"/>	
Difficulty Breathing	None <input checked="" type="radio"/>	
	Mild <input type="radio"/>	
	Moderate <input type="radio"/>	
	Severe <input type="radio"/>	
	Not Done <input type="radio"/>	
Fatigue	None <input checked="" type="radio"/>	
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Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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

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

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

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

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

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Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

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

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

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

Date	26 APR 2021
------	-------------

Assessment Not Done	False
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O2 Saturation	
---------------	--

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

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

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

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

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

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

Fatigue	None <input checked="" type="radio"/>
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Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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

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

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

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

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Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

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

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

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

Date	27 APR 2021
------	-------------

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

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

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

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

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

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

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

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

Fatigue	None <input checked="" type="radio"/>
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Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

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

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

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

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 APR 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	36.9 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
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Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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

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

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

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

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

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

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

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Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 APR 2021	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
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Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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

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

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

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

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

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Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

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

Date	30 APR 2021
------	-------------

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

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

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

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

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

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

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

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

Fatigue	None <input checked="" type="radio"/>
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Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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

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

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

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

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

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

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Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

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

Date	1 MAY 2021
------	------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

Fatigue	None <input type="checkbox"/>
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Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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

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

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

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

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

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

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

Date	2 MAY 2021
------	------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

Fatigue	None <input type="checkbox"/>
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Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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

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

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

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

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

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Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>
Day 33	<input type="checkbox"/>

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Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

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

Date	3 MAY 2021
------	------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

Fatigue	None <input type="checkbox"/>
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Form: Symptom Log (13)

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	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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

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

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

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

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

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>

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Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:09

Date of Visit	28 APR 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	28 APR 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 28 Apr 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:41:09

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 09 Jun 2021 15:41:09

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	30 APR 2021
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 APR 2021
Time of assessment (<i>00:00-23:59</i>)	11:34 (24 HR)
Vital Signs Date and Time (derived)	28 APR 2021 11:34
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 APR 2021

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

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Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:41:09

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 APR 2021

US3202191

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:09

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: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:41:09

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

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

Visit date (dd MMM yyyy)	6 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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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Date of updated informed consent (dd MMM yyyy) 06 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) 6 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 _____

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00-23:59)	13:14 (24 HR)
Collection date and time (derived)	6 JAN 2021 13:14

US3202191

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 JAN 2021
Collection time (00:00 - 23:59)	13:10
Collection Date and Time (derived)	6 JAN 2021 13:10

US3202191

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 13:09:29

Generated On: 09 Jun 2021 15:41:09

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

AEID

Adverse event

LACERATION OF RIGHT ELBOW

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

8 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)

08 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

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

US3202191

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

AEID

Adverse event

RIGHT OLECRANON BURSITIS
(RIGHT ELBOW INFECTION)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

27 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)

15 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

SUBJECT'S ELBOW
LACERATION BECAME
INFECTED AND SUBJECT
REPORTED HOSPITALIZATION
FOR THIS, BUT WHEN RECORDS
RECEIVED, THEY REVEALED
HE HAD A MINOR PROCEDURE
(INCISION AND DRAINAGE)
FOR THIS AE AND WAS NOT
ADMITTED. HIS
HOSPITALIZATION OCCURRED
A FEW DAYS LATER FOR
SEPARATE ISSUE --ADDING
THAT NOW. HE SEEMS TO
HAVE BEEN CONFUSED ABOUT
THE INDICATION FOR
HOSPITALIZATION AND/OR ITS
RELATIONSHIP TO THIS AE
BASED ON HIS INITIAL REPORT
OF EVENT.

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

AEID	USA-US128-2020-MRNA-1273-P30 1000009
Adverse event	WEAKNESS
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)	29 OCT 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)	03 NOV 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 checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	03 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

HE REPORTED
HOSPITALIZATION ON
19NOV2020 AND STATED IT
WAS RELATED TO INFECTED
WOUND ON RIGHT ELBOW,
WHICH WAS REPORTED AS THE
SAE W/IN 24 HOURS OF
KNOWLEDGE OF EVENT BY
SITE. MEDICAL RECORDS
REQUESTED AND RECEIVED BY
PI AND STUDY COORDINATOR
ON 24NOV2020. RECORDS
REVEALED THE
HOSPITALIZATION WAS DUE
TO WEAKNESS AND BALANCE
PROBLEMS RESULTING IN
MULTIPLE FALLS IN THE DAYS
FOLLOWING OUTPATIENT
PROCEDURE. FOR ELBOW
WOUND. HE WAS ADMITTED
FOR EVAL OF POSSIBLE
STROKE. RECORDS REVEALED
PRIOR CVA SUSPECTED IN
JUNE 2019 AND DIAGNOSIS OF
AXONAL NEUROPATHY. CT
HEAD W/O CONTRAST
IMPRESSION STATES "THERE IS
WHAT APPEARS TO BE A
SUBACUTE/CHRONIC
INFARCTION EVOLVING IN THE
POSTERIOR LEFT FRONTAL
LOBE. CHRONIC INFARCTION
IN THE LEFT CEREBELLAR
HEMISPHERE" PER RECORDS.
THE D/C DIAGNOSIS LISTED
STATES WEAKNESS AND
RECOMMENDED F/UP WITH HIS
CURRENT NEUROLOGIST.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

AEID	
Adverse event	URINARY RETENTION
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)	27 OCT 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 (4)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

AEID

Adverse event

L CUBITAL TUNNEL
SYNDROME

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)

02 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

2 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

AEID

Adverse event

ARTHRALGIA (JOINT ACHES)

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 AUG 2020

Start time (00:00-23:59)

21:00 (24 HR)

AE start date and time (derived)

14 AUG 2020 21:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 SEP 2020

End time (00:00-23:59)

07:00 (24 HR)

AE End Date and Time (derived)

12 SEP 2020 07:00

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3202191

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

AEID

Adverse event

MYALGIA (MUSCLE ACHES)

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 AUG 2020

Start time (00:00-23:59)

21:00 (24 HR)

AE start date and time (derived)

14 AUG 2020 21:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 SEP 2020

End time (00:00-23:59)

07:00 (24 HR)

AE End Date and Time (derived)

12 SEP 2020 07:00

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

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: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

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)	15 AUG 2020
Start time (00:00-23:59)	08:00 (24 HR)
AE start date and time (derived)	15 AUG 2020 08:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 SEP 2020
End time (00:00-23:59)	07:00 (24 HR)
AE End Date and Time (derived)	12 SEP 2020 07:00
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 (9)

Data signed: (b) (4) 22 Apr 2021 17:57:22

Generated On: 09 Jun 2021 15:41:09

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)	

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

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) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 JUN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 FEB 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

	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 SEP 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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 (4)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 JUN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication SOTALOL

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

	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 SEP 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication ANORA ELLIPTA

Prophylaxis Yes ☐
No ☒

Indication CHRONIC OBSTRUCTIVE
PULMONARY DISEASE

Dose per administration 62.5/25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication CELECOXIB

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

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 (7)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2004	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	03 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication JALYN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration 0.4/0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

	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)		21 NOV 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 (9)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication REGLAN

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1999
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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication NEXIUM

Prophylaxis Yes ☐
No ☒

Indication GERD

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 (10)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK	2004
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication HYDROCODONE/ACETAMINOP
HEN 10/325

Prophylaxis Yes ☐
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

	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)		06 APR 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication SULFAMETHOXAZOLE
TRIMETHOPRIM

Prophylaxis Yes ☐
No ☒

Indication LACERATION OF RIGHT ELBOW

Dose per administration 800/160

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) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

	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)	08 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)	29 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication RIGHT OLECRANON BURSITIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

	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)		08 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication DIPHENHYDRAMINE
HYDROCHLORIDE

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
SLEEPLESSNESS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

	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)	31 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)		02 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication LIDOCANE PATCH 5%

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN OSTEOARTHRITIS

Dose per administration 1

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

If dose unit is Other, specify PATCH

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication DEHISCENCE OF LEFT CUBITAL
TUNNEL RELEASE SUTURES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

	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)		10 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
27 OCT 2020	INCISION AND DRAINAGE OF OLECRANON BURSA	Adverse Event	
2 FEB 2021	LEFT CUBITAL TUNNEL RELEASE	Adverse Event	
9 MAR 2021	RESUTURE OF LEFT CUBITAL TUNNEL RELEASE SURGERY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:41:09

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:41:09

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 ☐

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Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

SAEID	USA-US128-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

SAEID	USA-US128-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	23/NOV/2020 16:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

SAEID	USA-US128-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	30/NOV/2020 09:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

SAEID	USA-US128-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	30/NOV/2020 13:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

SAEID	USA-US128-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	29/JAN/2021 13:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

SAEID	USA-US128-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	01/FEB/2021 12:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

SAEID	USA-US128-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	18/FEB/2021 15:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

SAEID	USA-US128-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	03/MAR/2021 13:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (8)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

SAEID	USA-US128-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	08/MAR/2021 09:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (9)

Data signed: (b) (4) 09 Apr 2021 15:35:12

Generated On: 09 Jun 2021 15:41:09

SAEID	USA-US128-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	08/MAR/2021 11:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3202191 (Prod: WR-ClinSearch, LLC)

US3202191

Form: Participant Creation

Generated On: 09 Jun 2021 15:41:09

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:41:29
User entered 'US3202191'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:29:23

US3202191

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	14 Aug 2020 17:25:30

US3202191

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:29:23

US3202191

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4)	14 Aug 2020 17:25:30

US3202191

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'SCRN'	System	14 Aug 2020 17:25:30

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered (b) (6) 1943'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:29:24

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '77'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:16:53

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'YEARS'	System	02 Sep 2020 22:16:53

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '77'	System	14 Aug 2020 17:25:42

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Male (M)'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:16:53

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:16:53

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'I'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:16:53

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	Erica Osmundsen (b) (4)	02 Sep 2020 22:16:53

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:16:53

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:16:53

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:16:53

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:16:53

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:16:53

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:16:53

US3202191

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:41:09

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Sep 2020 22:16:53

US3202191

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:09

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '14 Aug 2020'	Tiffany Jewell (b) (4)	14 Aug 2020 17:25:42

US3202191

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:09

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Aug 2020'	System	14 Aug 2020 17:25:42

US3202191

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:09

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2020'	System	14 Aug 2020 17:25:42

US3202191

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:09

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Amendment 2 (2)'	Tiffany Jewell (b) (4)	14 Aug 2020 17:25:42

US3202191

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:09

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	14 Aug 2020 17:25:42

US3202191

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:09

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	Tiffany Jewell (b) (4)	14 Aug 2020 17:25:42

US3202191

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:09

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	Tiffany Jewell (b) (4)	14 Aug 2020 17:25:42

US3202191

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:09

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'No (N)'	Tiffany Jewell (b) (4)	14 Aug 2020 17:25:42

US3202191

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:09

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:29:23

US3202191

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:41:09

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'I'	System	14 Aug 2020 17:25:49

US3202191

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:41:09

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	14 Aug 2020 17:25:49

US3202191

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:41:09

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:58:16

US3202191

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
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)	17 Sep 2020 22:29:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:29:42
Data point term sent to Coder	System	17 Sep 2020 22:28:45
User entered 'FATIGUE'	Erica Osmundsen (b) (4)	17 Sep 2020 22:28:14

US3202191

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN UNK 2018'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:28:14

US3202191

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:28:14

US3202191

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:28:14

US3202191

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:28:14

US3202191

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:28:14

US3202191

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jan 2018'	System	17 Sep 2020 22:28:14

US3202191

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2018'	System	17 Sep 2020 22:28:14

US3202191

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:28:14

US3202191

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:28:14

US3202191

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:29:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:29:42
Data point term sent to Coder	System	17 Sep 2020 22:28:46
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Erica Osmundsen (b) (4)	17 Sep 2020 22:28:44

US3202191

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN UNK 2018'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:28:44

US3202191

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:28:44

US3202191

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:28:44

US3202191

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:28:44

US3202191

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:28:44

US3202191

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jan 2018'	System	17 Sep 2020 22:28:44

US3202191

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2018'	System	17 Sep 2020 22:28:44

US3202191

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:28:44

US3202191

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:28:44

US3202191

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:30:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:30:44
Data point term sent to Coder	System	17 Sep 2020 22:29:47
User entered 'ATRIAL FIBRILLATION'	Erica Osmundsen (b) (4)	17 Sep 2020 22:29:10

US3202191

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN Sep 2019' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:38:42
User entered 'UN UNK 2019'	Erica Osmundsen (b) (4)	17 Sep 2020 22:29:10

US3202191

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:29:10

US3202191

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:29:10

US3202191

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:29:10

US3202191

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:29:10

US3202191

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Sep 2019'	System	17 Sep 2020 22:38:42
User entered 'Jan 2019'	System	17 Sep 2020 22:29:10

US3202191

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2019'	System	17 Sep 2020 22:29:10

US3202191

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:29:10

US3202191

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:29:10

US3202191

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:30:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:30:44
Data point term sent to Coder	System	17 Sep 2020 22:29:47
User entered 'HYPERTENSION'	Erica Osmundsen (b) (4)	17 Sep 2020 22:29:29

US3202191

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN UNK 2016'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:29:29

US3202191

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:29:29

US3202191

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:29:29

US3202191

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:29:29

US3202191

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:29:29

US3202191

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jan 2016'	System	17 Sep 2020 22:29:29

US3202191

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2016'	System	17 Sep 2020 22:29:29

US3202191

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:29:29

US3202191

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:29:29

US3202191

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema legs - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 06:21:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 06:21:48
Data point term sent to Coder	System	17 Sep 2020 22:30:52
User entered 'EPISODIC EDEMA BILATERAL LEGS'	Erica Osmundsen (b) (4)	17 Sep 2020 22:30:49

US3202191

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN UNK 2016'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:30:49

US3202191

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:30:49

US3202191

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:30:49

US3202191

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:30:49

US3202191

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:30:49

US3202191

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jan 2016'	System	17 Sep 2020 22:30:49

US3202191

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2016'	System	17 Sep 2020 22:30:49

US3202191

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:30:49

US3202191

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:30:49

US3202191

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: Investigations, HLG: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:32:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:32:42
Data point term sent to Coder	System	17 Sep 2020 22:31:52
User entered 'HIGH CHOLESTEROL'	Erica Osmundsen (b) (4)	17 Sep 2020 22:31:03

US3202191

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN UNK 2016'	Erica Osmundsen (b) (4)	17 Sep 2020 22:31:03

US3202191

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:31:03

US3202191

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:31:03

US3202191

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:31:03

US3202191

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:31:03

US3202191

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jan 2016'	System	17 Sep 2020 22:31:03

US3202191

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2016'	System	17 Sep 2020 22:31:03

US3202191

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:31:03

US3202191

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:31:03

US3202191

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:32:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:32:42
Data point term sent to Coder	System	17 Sep 2020 22:31:55
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Erica Osmundsen (b) (4)	17 Sep 2020 22:31:51

US3202191

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN UNK 1999'	Erica Osmundsen (b) (4)	17 Sep 2020 22:31:51

US3202191

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:31:51

US3202191

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:31:51

US3202191

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:31:51

US3202191

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:31:51

US3202191

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jan 1999'	System	17 Sep 2020 22:31:51

US3202191

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '1999'	System	17 Sep 2020 22:31:51

US3202191

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:31:51

US3202191

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:31:51

US3202191

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:40:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:40:39
Data point term sent to Coder	System	17 Sep 2020 22:40:03
User entered 'HIATAL HERNIA' reason for change:	Erica Osmundsen (b) (4)	17 Sep 2020 22:39:25
Data Entry Error		
Data point term sent to Coder	System	17 Sep 2020 22:32:56
User entered 'HIATA; HERNIA'	Erica Osmundsen (b) (4)	17 Sep 2020 22:32:11

US3202191

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN UNK 2000'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:32:11

US3202191

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:32:11

US3202191

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:32:11

US3202191

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:32:11

US3202191

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:32:11

US3202191

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jan 2000'	System	17 Sep 2020 22:32:11

US3202191

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2000'	System	17 Sep 2020 22:32:11

US3202191

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:32:11

US3202191

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:32:11

US3202191

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:42:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:42:43
Data point term sent to Coder	System	17 Sep 2020 22:42:07
Coding entries removed.	Erica Osmundsen (b) (4)	17 Sep 2020 22:41:21
User entered 'BENIGN PROSTATIC HYPERPLASIA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	17 Sep 2020 22:41:21
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:33:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:33:47
Data point term sent to Coder	System	17 Sep 2020 22:32:55
User entered 'ENLARGED PROSTATE'	Erica Osmundsen (b) (4)	17 Sep 2020 22:32:28

US3202191

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN UNK 2012'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:32:28

US3202191

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:32:28

US3202191

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:32:28

US3202191

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:32:28

US3202191

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:32:28

US3202191

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jan 2012'	System	17 Sep 2020 22:32:28

US3202191

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2012'	System	17 Sep 2020 22:32:28

US3202191

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:32:28

US3202191

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:32:28

US3202191

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis shoulders - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 05:42:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 05:42:52
Data point term sent to Coder	System	17 Sep 2020 22:33:57
User entered 'OSTEOARTHRITIS IN SHOULDERS BILATERAL'	Erica Osmundsen (b) (4)	17 Sep 2020 22:33:31

US3202191

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN UNK 2004'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:33:31

US3202191

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:33:31

US3202191

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:33:31

US3202191

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:33:31

US3202191

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:33:31

US3202191

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jan 2004'	System	17 Sep 2020 22:33:31

US3202191

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2004'	System	17 Sep 2020 22:33:31

US3202191

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:33:31

US3202191

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:33:31

US3202191

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:41:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:35:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:35:43
Data point term sent to Coder	System	17 Sep 2020 22:34:58
User entered 'OBESITY'	Erica Osmundsen (b) (4)	17 Sep 2020 22:34:08

US3202191

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN UNK 1950'	Erica Osmundsen (b) (4)	17 Sep 2020 22:34:08

US3202191

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:34:08

US3202191

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:34:08

US3202191

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:34:08

US3202191

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:34:08

US3202191

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jan 1950'	System	17 Sep 2020 22:34:08

US3202191

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '1950'	System	17 Sep 2020 22:34:08

US3202191

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:34:08

US3202191

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:34:08

US3202191

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:41:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Olfactory nerve disorders, PT: Anosmia, LLT: Anosmia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:35:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:35:42
Data point term sent to Coder	System	17 Sep 2020 22:34:58
User entered 'Anosmia'	Erica Osmundsen (b) (4)	17 Sep 2020 22:34:35

US3202191

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN UNK 1943'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:34:35

US3202191

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:34:35

US3202191

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:34:35

US3202191

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:34:35

US3202191

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:34:35

US3202191

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered (b) (6) 1943'	System	17 Sep 2020 22:34:35

US3202191

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '1943'	System	17 Sep 2020 22:34:35

US3202191

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:34:35

US3202191

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:34:35

US3202191

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:41:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Axonal neuropathy, LLT: Axonal neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 14:15:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 14:15:18
Data point term sent to Coder	System	25 Nov 2020 14:13:58
Coding entries removed.	Erica Osmundsen (b) (4)	25 Nov 2020 14:13:15
User entered 'AXONAL NEUROPATHY' reason for change: New Information	Erica Osmundsen (b) (4)	25 Nov 2020 14:13:15
Query 'Per DM CLR: Please verify the TYPE OF NEUROPATHY (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:58:20
User opened query 'Per DM CLR: Please verify the TYPE OF NEUROPATHY (i.e. sensory or motor). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:48:19
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy peripheral - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 05:45:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 05:45:43
Data point term sent to Coder	System	17 Sep 2020 22:35:59
User entered 'NEUROPATHY LEGS BILATERAL'	Erica Osmundsen (b) (4)	17 Sep 2020 22:35:21

US3202191

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN Jun 2019' reason for change: New Information	(b) (4) Erica Osmundsen (b) (4)	25 Nov 2020 14:13:15
User entered 'UN UNK 2019'	Erica Osmundsen (b) (4)	17 Sep 2020 22:35:21

US3202191

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:35:21

US3202191

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:35:21

US3202191

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:35:21

US3202191

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:35:21

US3202191

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jun 2019'	System	25 Nov 2020 14:13:15
User entered 'Jan 2019'	System	17 Sep 2020 22:35:21

US3202191

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2019'	System	17 Sep 2020 22:35:21

US3202191

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:35:21

US3202191

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:35:21

US3202191

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:41:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Ankle osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:38:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 22:38:47
Data point term sent to Coder	System	17 Sep 2020 22:38:01
User entered 'OSTEOARTHRITIS RIGHT ANKLE'	Erica Osmundsen (b) (4)	17 Sep 2020 22:37:19

US3202191

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN UNK 2004'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:37:19

US3202191

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:37:19

US3202191

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:37:19

US3202191

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:37:19

US3202191

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:37:19

US3202191

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jan 2004'	System	17 Sep 2020 22:37:19

US3202191

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2004'	System	17 Sep 2020 22:37:19

US3202191

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:37:19

US3202191

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:37:19

US3202191

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:41:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
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: Lumbar disc degeneration - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 06:30:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 06:30:45
Data point term sent to Coder	System	17 Sep 2020 22:39:02
User entered 'DEGENERATIVE DISC DISEASE LUMBAR SPINE'	Erica Osmundsen (b) (4)	17 Sep 2020 22:38:22

US3202191

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN UNK 1983'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:38:22

US3202191

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:38:22

US3202191

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:38:22

US3202191

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:38:22

US3202191

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:38:22

US3202191

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jan 1983'	System	17 Sep 2020 22:38:22

US3202191

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '1983'	System	17 Sep 2020 22:38:22

US3202191

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:38:22

US3202191

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	17 Sep 2020 22:38:22

US3202191

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:41:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 14:26:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 14:26:15
Data point term sent to Coder	System	25 Nov 2020 14:25:09
User entered 'CEREBRAL VASCULAR ACCIDENT'	Erica Osmundsen (b) (4)	25 Nov 2020 14:24:13

US3202191

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN Jun 2019' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	25 Nov 2020 14:25:01
User entered 'UN UNK 2019'	Erica Osmundsen (b) (4)	25 Nov 2020 14:24:13

US3202191

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	25 Nov 2020 14:24:13

US3202191

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4) System	25 Nov 2020 14:25:01
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	25 Nov 2020 14:24:13
User entered 'No (N)'	Erica Osmundsen (b) (4)	25 Nov 2020 14:24:13

US3202191

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN Jun 2019' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	25 Nov 2020 14:25:01
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 14:24:13

US3202191

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	25 Nov 2020 14:24:13

US3202191

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jun 2019'	System	25 Nov 2020 14:25:01
User entered 'Jan 2019'	System	25 Nov 2020 14:24:13

US3202191

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2019'	System	25 Nov 2020 14:24:13

US3202191

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jun 2019'	System	25 Nov 2020 14:25:01
User entered empty.	System	25 Nov 2020 14:24:13

US3202191

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2019'	System	25 Nov 2020 14:25:01
User entered empty.	System	25 Nov 2020 14:24:13

US3202191

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:41:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Gait disturbances, PT: Gait disturbance, LLT: Gait disturbance - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 14:27:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 14:27:19
Data point term sent to Coder	System	25 Nov 2020 14:26:09
User entered 'GAIT DISTURBANCE'	Erica Osmundsen (b) (4)	25 Nov 2020 14:25:22

US3202191

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'UN Jun 2019'	(b) (4) Erica Osmundsen (b) (4)	25 Nov 2020 14:25:22

US3202191

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	25 Nov 2020 14:25:22

US3202191

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	25 Nov 2020 14:25:22

US3202191

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	25 Nov 2020 14:25:22

US3202191

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	25 Nov 2020 14:25:22

US3202191

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'Jun 2019'	System	25 Nov 2020 14:25:22

US3202191

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '2019'	System	25 Nov 2020 14:25:22

US3202191

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	25 Nov 2020 14:25:22

US3202191

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	25 Nov 2020 14:25:22

US3202191

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:41:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebral infarction, LLT: Posterior cerebral artery infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 16:23:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 16:23:51
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:11:02
Data point term sent to Coder	System	29 Jan 2021 17:01:01
User entered 'Subacute chronic infarction in left posterior lobe'	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:00:36

US3202191

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) zackery harmon (b) (4)	29 Jan 2021 17:00:36

US3202191

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'I'	(b) (4) zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:00:36

US3202191

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	29 Jan 2021 17:00:36

US3202191

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) zackery harmon (b) (4)	29 Jan 2021 17:00:36

US3202191

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) zackery harmon (b) (4)	29 Jan 2021 17:00:36

US3202191

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	29 Jan 2021 17:00:36

US3202191

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	29 Jan 2021 17:00:36

US3202191

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	29 Jan 2021 17:00:36

US3202191

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	29 Jan 2021 17:00:36

US3202191

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:41:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebellar infarction, LLT: Cerebellar infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:27:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:27:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	13 Feb 2021 02:11:02
Data point term sent to Coder	System	29 Jan 2021 17:02:02
User entered 'Chronic infarction in left cerebellar hemisphere'	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:01:02

US3202191

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) zackery harmon (b) (4)	29 Jan 2021 17:01:02

US3202191

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'I'	(b) (4) zackery harmon (b) (4)	29 Jan 2021 17:01:02

US3202191

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	29 Jan 2021 17:01:02

US3202191

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) zackery harmon (b) (4)	29 Jan 2021 17:01:02

US3202191

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '0'	(b) (4) zackery harmon (b) (4)	29 Jan 2021 17:01:02

US3202191

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:41:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	29 Jan 2021 17:01:02

US3202191

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	29 Jan 2021 17:01:02

US3202191

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	29 Jan 2021 17:01:02

US3202191

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered empty.	System	29 Jan 2021 17:01:02

US3202191

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:41:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10

US3202191

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10

US3202191

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10

US3202191

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:41:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10

US3202191

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:41:09

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10

US3202191

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:41:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10

US3202191

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:41:09

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10

US3202191

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:41:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10

US3202191

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:41:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10

US3202191

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:41:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '12:40'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered '14 Aug 2020 12:40'	System	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '183.0' cm	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:00:19
DataPoint set to visible.	(b) (4) System	14 Aug 2020 17:25:49

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '150.0' kg	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:00:19
DataPoint set to visible.	(b) (4) System	14 Aug 2020 17:25:49

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User closed query 'Per CDM: per sponsor review, BMI \geq 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:38:25
Query 'Per CDM: per sponsor review, BMI \geq 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	07 Apr 2021 15:34:54
User opened query 'Per CDM: per sponsor review, BMI \geq 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:18:32
User entered '44.79083'	System	06 Sep 2020 17:00:19
DataPoint set to visible.	System	14 Aug 2020 17:25:49

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'kg/m2'	System	06 Sep 2020 17:00:19
DataPoint set to visible.	System	14 Aug 2020 17:25:49

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'bpm'	System	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'breaths/min'	System	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'mmHg'	System	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User entered 'mmHg'	System	06 Sep 2020 17:00:19

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10

US3202191

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10

US3202191

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:58:36

US3202191

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:58:36

US3202191

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:09

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:59:29

US3202191

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:09

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:59:29

US3202191

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:09

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:59:29

US3202191

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:09

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:59:29

US3202191

Folder: Screening

Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:59:29

US3202191

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:09

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:59:29

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:09

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	zackery harmon (b) (4)	06 Sep 2020 16:59:29

US3202191

Folder: Screening

Form: Risk of Exposure

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[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:59:29

US3202191

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:09

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:59:29

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:59:29

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	zackery harmon (b) (4)	06 Sep 2020 16:59:29

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:59:29

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:59:29

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '0'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:59:29

US3202191

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:09

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '0'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:59:29

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Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:59:29

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:09

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '0'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:59:29

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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '0'	zackery harmon (b) (4)	06 Sep 2020 16:59:29

US3202191

Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'I'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 16:59:29

US3202191

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'I'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:59:29

US3202191

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:41:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:35:10
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Plans on routinely going to places where people gather'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 16:59:29

US3202191

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:00:36

US3202191

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:00:36
	(b) (4)	

US3202191

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Clinic (Clinic)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:00:36

US3202191

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'VISIT1'	System	06 Sep 2020 17:00:36

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:50:12

US3202191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:09

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:34:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:34:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 16:50:12
User entered '186327' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:50:12

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:09

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:50:12

US3202191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:09

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User closed query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Sep 2020 11:27:19
Query ' PER CDM: Please complete this section of the form' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	03 Sep 2020 11:59:39
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	03 Sep 2020 11:59:35
User opened query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 17:24:06

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:09

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	03 Sep 2020 11:59:35

US3202191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:09

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	03 Sep 2020 11:59:35

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:09

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	03 Sep 2020 11:59:35

US3202191

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:09

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	03 Sep 2020 11:59:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:41:09

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 14:17:46
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:21:06
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:19:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4)	06 Sep 2020 17:02:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:02:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '12:40'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:02:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered '14 Aug 2020 12:40'	System	06 Sep 2020 17:02:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '36.8' C	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:02:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '65'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'bpm'	System	06 Sep 2020 17:02:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '18'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:02:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'breaths/min'	System	06 Sep 2020 17:02:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '152'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'mmHg'	System	06 Sep 2020 17:02:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '82'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:02:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'mmHg'	System	06 Sep 2020 17:02:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:41:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:02:33

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33
	(b) (4)	

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:02:33

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '14:06'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:02:33

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered '14 Aug 2020 14:06'	System	06 Sep 2020 17:02:33

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '37.0' C	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:02:33

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33
	(b) (4)	

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '60'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:02:33

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'bpm'	System	06 Sep 2020 17:02:33

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '18'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:02:33
	(b) (4)	

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'breaths/min'	System	06 Sep 2020 17:02:33

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:49:26
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:02:44
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	06 Sep 2020 17:02:33
User entered '156'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:02:33

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'mmHg'	System	06 Sep 2020 17:02:33

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '84'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:02:33

US3202191

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'mmHg'	System	06 Sep 2020 17:02:33

US3202191

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:01:16

US3202191

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:01:16

US3202191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	14 Aug 2020 17:26:21

US3202191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	14 Aug 2020 17:26:21

US3202191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	Tiffany Jewell (b) (4)	14 Aug 2020 17:26:21

US3202191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 17:26:21

US3202191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '14 Aug 2020'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 17:26:21

US3202191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '13:19'	(b) (4) Tiffany Jewell (b) (4)	14 Aug 2020 17:26:21

US3202191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered '14 Aug 2020 13:19'	System	14 Aug 2020 17:26:21

US3202191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tiffany Jewell (b) (4)	14 Aug 2020 17:26:21

US3202191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'ONCE'	System	14 Aug 2020 17:26:21

US3202191

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 17:26:21

US3202191

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:00:52

US3202191

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:00:52
	(b) (4)	

US3202191

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '12:57'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:00:52

US3202191

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered '14 Aug 2020 12:57'	System	06 Sep 2020 17:00:52

US3202191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:41:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:01:06

US3202191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:01:06

US3202191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:01:06

US3202191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:09

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '12:55'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 17:01:06

US3202191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered '14 Aug 2020 12:55'	System	06 Sep 2020 17:01:06

US3202191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	zackery harmon (b) (4)	06 Sep 2020 17:01:06

US3202191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:01:06
	(b) (4)	

US3202191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:09

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) zackery harmon (b) (4)	06 Sep 2020 17:01:06

US3202191

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered empty.	System	06 Sep 2020 17:01:06

US3202191

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	24 Aug 2020 17:09:28

US3202191

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'I'	System	24 Aug 2020 17:09:28

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:11:28', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '0369802b-62d4-4f3c-9e6e-de9a0559b243'	System	14 Aug 2020 18:15:37
User entered 'Yes (Y)'	System	14 Aug 2020 18:15:37

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:11:41', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '0369802b-62d4-4f3c-9e6e-de9a0559b243'	System	14 Aug 2020 18:15:37
User entered '98.6'	System	14 Aug 2020 18:15:37

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:12:08', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '0369802b-62d4-4f3c-9e6e-de9a0559b243'	System	14 Aug 2020 18:15:37
User entered 'No (N)'	System	14 Aug 2020 18:15:37

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:12:24', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '0369802b-62d4-4f3c-9e6e-de9a0559b243'	System	14 Aug 2020 18:15:37
User entered '14 Aug 2020 14:12'	System	14 Aug 2020 18:15:37

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Aug 2020 13:39'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Aug 2020 16:09'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:08:39', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '45012046-3e73-46a8-b42d-1280011968b9'	System	14 Aug 2020 21:10:46
User entered 'Yes (Y)'	System	14 Aug 2020 21:10:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:10:30', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '45012046-3e73-46a8-b42d-1280011968b9'	System	14 Aug 2020 21:10:46
User entered '97.5'	System	14 Aug 2020 21:10:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:10:35', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '45012046-3e73-46a8-b42d-1280011968b9'	System	14 Aug 2020 21:10:46
User entered 'No (N)'	System	14 Aug 2020 21:10:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:10:43', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '45012046-3e73-46a8-b42d-1280011968b9'	System	14 Aug 2020 21:10:46
User entered '14 Aug 2020 17:10'	System	14 Aug 2020 21:10:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Aug 2020 17:04'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 2'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:16:15', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ff113b84-cd7d-4f2f-9207-b7eabdd35f27'	System	15 Aug 2020 17:16:55
User entered 'Yes (Y)'	System	15 Aug 2020 17:16:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:16:22', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ff113b84-cd7d-4f2f-9207-b7eabdd35f27'	System	15 Aug 2020 17:16:55
User entered '98.0'	System	15 Aug 2020 17:16:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:16:31', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ff113b84-cd7d-4f2f-9207-b7eabdd35f27'	System	15 Aug 2020 17:16:55
User entered 'Yes (Y)'	System	15 Aug 2020 17:16:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject says he is on celebrex for arthritis which is not related to the vaccine. He miss understood the question and made several erroneous entries' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:11:50
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).	Lilian Nukuna (b) (4)	24 Aug 2020 17:01:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:16:44', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ff113b84-cd7d-4f2f-9207-b7eabdd35f27'	(b) (4)	
User entered '1'	System	15 Aug 2020 17:16:55
	System	15 Aug 2020 17:16:55
	System	15 Aug 2020 17:16:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:11:54
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 (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:16:44', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ff113b84-cd7d-4f2f-9207-b7eabdd35f27'	Lilian Nukuna (b) (4)	24 Aug 2020 17:01:27
User entered '1'	System	15 Aug 2020 17:16:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:16:52', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ff113b84-cd7d-4f2f-9207-b7eabdd35f27'	System	15 Aug 2020 17:16:55
User entered '15 Aug 2020 12:16'	System	15 Aug 2020 17:16:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 3'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:06:45', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3051990f-de9d-4179-81cb-573a908ea750'	System	16 Aug 2020 17:10:13
User entered 'Yes (Y)'	System	16 Aug 2020 17:10:13

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:09:39', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3051990f-de9d-4179-81cb-573a908ea750'	System	16 Aug 2020 17:10:13
User entered '97.9'	System	16 Aug 2020 17:10:13

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:09:53', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3051990f-de9d-4179-81cb-573a908ea750'	System	16 Aug 2020 17:10:13
User entered 'Yes (Y)'	System	16 Aug 2020 17:10:13

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:14:17
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 (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:10:03', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3051990f-de9d-4179-81cb-573a908ea750'	Lilian Nukuna (b) (4)	24 Aug 2020 17:02:03
User entered '1'	System	16 Aug 2020 17:10:13

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:14:19
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 (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:10:03', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3051990f-de9d-4179-81cb-573a908ea750'	Lilian Nukuna (b) (4)	24 Aug 2020 17:02:01
User entered '1'	(b) (4)	
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).	System	16 Aug 2020 17:10:13
User entered '1'	System	16 Aug 2020 17:10:13

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:10:12', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3051990f-de9d-4179-81cb-573a908ea750'	System	16 Aug 2020 17:10:13
User entered '16 Aug 2020 12:10'	System	16 Aug 2020 17:10:13

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 4'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:30:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '2091aab3-a9a2-49ff-9f9d-0b7e17b299d7'	System	17 Aug 2020 17:30:49
User entered 'Yes (Y)'	System	17 Aug 2020 17:30:49

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:30:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '2091aab3-a9a2-49ff-9f9d-0b7e17b299d7'	System	17 Aug 2020 17:30:49
User entered '97.8'	System	17 Aug 2020 17:30:49

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:30:35', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '2091aab3-a9a2-49ff-9f9d-0b7e17b299d7'	System	17 Aug 2020 17:30:49
User entered 'Yes (Y)'	System	17 Aug 2020 17:30:49

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'entries were made in error. He had no post vaccine adverse effects' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:14:30
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).	Lilian Nukuna (b) (4)	24 Aug 2020 17:02:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:30:39', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '2091aab3-a9a2-49ff-9f9d-0b7e17b299d7'	(b) (4)	
User entered '1'	System	17 Aug 2020 17:30:49
	System	17 Aug 2020 17:30:49
	System	17 Aug 2020 17:30:49

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'data was entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:14:34
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 'data was entered in error' (Site from System).	Lilian Nukuna (b) (4) (b) (4)	24 Aug 2020 17:03:06
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).	System	17 Aug 2020 17:30:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:30:39', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '2091aab3-a9a2-49ff-9f9d-0b7e17b299d7'	System	17 Aug 2020 17:30:49
User entered '1'	System	17 Aug 2020 17:30:49

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:30:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '2091aab3-a9a2-49ff-9f9d-0b7e17b299d7'	System	17 Aug 2020 17:30:49
User entered '17 Aug 2020 12:30'	System	17 Aug 2020 17:30:49

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 5'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:08:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '571df4e2-c040-47e2-b7ee-1d1732cd6ded'	System	18 Aug 2020 17:08:52
User entered 'Yes (Y)'	System	18 Aug 2020 17:08:52

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:08:24', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '571df4e2-c040-47e2-b7ee-1d1732cd6ded' User entered '97.7'	System	18 Aug 2020 17:08:52
	System	18 Aug 2020 17:08:52

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:08:29', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '571df4e2-c040-47e2-b7ee-1d1732cd6ded'	System	18 Aug 2020 17:08:52
User entered 'Yes (Y)'	System	18 Aug 2020 17:08:52

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'data was entered in error per subject' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:14:41
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.'	Lilian Nukuna (b) (4)	24 Aug 2020 17:03:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:08:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '571df4e2-c040-47e2-b7ee-1d1732cd6ded'	(b) (4)	
User entered '1'	System	18 Aug 2020 17:08:52
	System	18 Aug 2020 17:08:52
	System	18 Aug 2020 17:08:52

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject stated data was entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:14:44
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 'subject stated data was entered in error' (Site from System).	Lilian Nukuna (b) (4)	24 Aug 2020 17:03:59
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).	System	18 Aug 2020 17:08:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:08:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '571df4e2-c040-47e2-b7ee-1d1732cd6ded'	System	18 Aug 2020 17:08:52
User entered '1'	System	18 Aug 2020 17:08:52

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:08:49', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '571df4e2-c040-47e2-b7ee-1d1732cd6ded'	System	18 Aug 2020 17:08:52
User entered '18 Aug 2020 12:08'	System	18 Aug 2020 17:08:52

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 6'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:18:50', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a63a94fa-bb61-4835-aaa0-dc5dba3619c7'	System	19 Aug 2020 17:19:17
User entered 'Yes (Y)'	System	19 Aug 2020 17:19:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:18:57', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a63a94fa-bb61-4835-aaa0-dc5dba3619c7'	System	19 Aug 2020 17:19:17
User entered '97.7'	System	19 Aug 2020 17:19:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:19:03', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a63a94fa-bb61-4835-aaa0-dc5dba3619c7'	System	19 Aug 2020 17:19:17
User entered 'Yes (Y)'	System	19 Aug 2020 17:19:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'data was entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:15:01
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.'	Lilian Nukuna (b) (4)	24 Aug 2020 17:04:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:19:09', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a63a94fa-bb61-4835-aaa0-dc5dba3619c7'	(b) (4)	
User entered '1'	System	19 Aug 2020 17:19:17
	System	19 Aug 2020 17:19:17
	System	19 Aug 2020 17:19:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'data was entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:15:04
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 'data was entered in error' (Site from System).	Lilian Nukuna (b) (4) (b) (4)	24 Aug 2020 17:04:39
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).	System	19 Aug 2020 17:19:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:19:09', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a63a94fa-bb61-4835-aaa0-dc5dba3619c7'	System	19 Aug 2020 17:19:17
User entered '1'	System	19 Aug 2020 17:19:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:19:15', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a63a94fa-bb61-4835-aaa0-dc5dba3619c7'	System	19 Aug 2020 17:19:17
User entered '19 Aug 2020 12:19'	System	19 Aug 2020 17:19:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 7'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:35:53', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e4f3621c-5bc5-4bf6-806c-f614a142c4a9'	System	20 Aug 2020 18:36:17
User entered 'Yes (Y)'	System	20 Aug 2020 18:36:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:36:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e4f3621c-5bc5-4bf6-806c-f614a142c4a9'	System	20 Aug 2020 18:36:17
User entered '98.1'	System	20 Aug 2020 18:36:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:36:04', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e4f3621c-5bc5-4bf6-806c-f614a142c4a9'	System	20 Aug 2020 18:36:17
User entered 'Yes (Y)'	System	20 Aug 2020 18:36:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject sated that data was entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:15:12
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).	Lilian Nukuna (b) (4)	24 Aug 2020 17:05:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:36:08', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e4f3621c-5bc5-4bf6-806c-f614a142c4a9'	(b) (4)	
User entered '1'	System	20 Aug 2020 18:36:17
	System	20 Aug 2020 18:36:17
	System	20 Aug 2020 18:36:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject stated that data was entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:15:15
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).	Lilian Nukuna (b) (4)	24 Aug 2020 17:05:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:36:08', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e4f3621c-5bc5-4bf6-806c-f614a142c4a9'	(b) (4)	
User entered '1'	System	20 Aug 2020 18:36:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:36:15', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e4f3621c-5bc5-4bf6-806c-f614a142c4a9'	System	20 Aug 2020 18:36:17
User entered '20 Aug 2020 14:36'	System	20 Aug 2020 18:36:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	19 Aug 2020 17:19:17
User entered 'Day 8'	System	19 Aug 2020 17:19:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-21T12:02:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b666462e-5e89-47ba-9c48-8cebaa8e51c0'	System	21 Aug 2020 16:03:01
User entered 'Yes (Y)'	System	21 Aug 2020 16:03:01

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-21T12:02:42', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b666462e-5e89-47ba-9c48-8cebaa8e51c0'	System	21 Aug 2020 16:03:01
User entered '97.6'	System	21 Aug 2020 16:03:01

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-21T12:02:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b666462e-5e89-47ba-9c48-8cebaa8e51c0'	System	21 Aug 2020 16:03:01
User entered 'Yes (Y)'	System	21 Aug 2020 16:03:01

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject stated that data was entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:15:28
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).	Lilian Nukuna (b) (4)	24 Aug 2020 17:05:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-21T12:02:50', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b666462e-5e89-47ba-9c48-8cebaa8e51c0'	(b) (4)	
User entered '1'	System	21 Aug 2020 16:03:01
	System	21 Aug 2020 16:03:01
	System	21 Aug 2020 16:03:01

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'data was entered in error' (Site from System).	(b) (4), (b) (6)	04 Sep 2020 11:27:39
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).	Lilian Nukuna (b) (4)	24 Aug 2020 17:06:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-21T12:02:50', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b666462e-5e89-47ba-9c48-8cebaa8e51c0'	(b) (4)	
User entered '1'	System	21 Aug 2020 16:03:01

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-21T12:02:55', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b666462e-5e89-47ba-9c48-8cebaa8e51c0'	System	21 Aug 2020 16:03:01
User entered '21 Aug 2020 12:02'	System	21 Aug 2020 16:03:01

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:19:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:19:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	20 Aug 2020 18:36:17
User entered 'Day 9'	System	20 Aug 2020 18:36:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-22T13:10:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e90a01a3-5347-470b-a37b-290992734168'	System	22 Aug 2020 17:10:47
User entered 'Yes (Y)'	System	22 Aug 2020 17:10:47

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-22T13:10:29', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e90a01a3-5347-470b-a37b-290992734168' User entered '97.9'	System	22 Aug 2020 17:10:47
	System	22 Aug 2020 17:10:47

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-22T13:10:33', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e90a01a3-5347-470b-a37b-290992734168'	System	22 Aug 2020 17:10:47
User entered 'Yes (Y)'	System	22 Aug 2020 17:10:47

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject stated that data was entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:15:38
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).	Lilian Nukuna (b) (4)	24 Aug 2020 17:06:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-22T13:10:37', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e90a01a3-5347-470b-a37b-290992734168'	(b) (4)	
User entered '1'	System	22 Aug 2020 17:10:47

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject stated that data was entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:15:41
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).	Lilian Nukuna (b) (4)	24 Aug 2020 17:07:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-22T13:10:37', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e90a01a3-5347-470b-a37b-290992734168'	(b) (4)	
User entered '1'	System	22 Aug 2020 17:10:47
	System	22 Aug 2020 17:10:47
	System	22 Aug 2020 17:10:47

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-22T13:10:42', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e90a01a3-5347-470b-a37b-290992734168'	System	22 Aug 2020 17:10:47
User entered '22 Aug 2020 13:10'	System	22 Aug 2020 17:10:47

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 18:36:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 18:36:17

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	21 Aug 2020 16:03:01
User entered 'Day 10'	System	21 Aug 2020 16:03:01

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-23T12:02:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '15c8bb4e-82e9-407a-bc67-63a6ac0491d2'	System	23 Aug 2020 16:02:26
User entered 'Yes (Y)'	System	23 Aug 2020 16:02:26

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-23T12:02:10', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '15c8bb4e-82e9-407a-bc67-63a6ac0491d2'	System	23 Aug 2020 16:02:26
User entered '97.8'	System	23 Aug 2020 16:02:26

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-23T12:02:13', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '15c8bb4e-82e9-407a-bc67-63a6ac0491d2'	System	23 Aug 2020 16:02:26
User entered 'Yes (Y)'	System	23 Aug 2020 16:02:26

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject stated that data was entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:15:50
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).	Lilian Nukuna (b) (4)	24 Aug 2020 17:07:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-23T12:02:16', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '15c8bb4e-82e9-407a-bc67-63a6ac0491d2'	(b) (4)	
User entered '1'	System	23 Aug 2020 16:02:26
	System	23 Aug 2020 16:02:26
	System	23 Aug 2020 16:02:26

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'data was entered in error per subject' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:15:52
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 'data was entered in error per subject' (Site from System).	Lilian Nukuna (b) (4)	24 Aug 2020 17:07:43
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).	System	23 Aug 2020 16:02:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-23T12:02:16', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '15c8bb4e-82e9-407a-bc67-63a6ac0491d2'	System	23 Aug 2020 16:02:26
User entered '1'	System	23 Aug 2020 16:02:26

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-23T12:02:21', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '15c8bb4e-82e9-407a-bc67-63a6ac0491d2'	System	23 Aug 2020 16:02:26
User entered '23 Aug 2020 12:02'	System	23 Aug 2020 16:02:26

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:03:01

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:03:01

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	22 Aug 2020 17:10:47
User entered 'Day 11'	System	22 Aug 2020 17:10:47

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-24T12:02:30', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cbe4b020-2488-458c-a0ff-a4d83b394ef9'	System	24 Aug 2020 16:02:59
User entered 'Yes (Y)'	System	24 Aug 2020 16:02:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-24T12:02:40', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cbe4b020-2488-458c-a0ff-a4d83b394ef9'	System	24 Aug 2020 16:02:59
User entered '97.6'	System	24 Aug 2020 16:02:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-24T12:02:44', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cbe4b020-2488-458c-a0ff-a4d83b394ef9'	System	24 Aug 2020 16:02:59
User entered 'Yes (Y)'	System	24 Aug 2020 16:02:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject sated that data was entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:16:02
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).	Lilian Nukuna (b) (4)	24 Aug 2020 17:08:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-24T12:02:47', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cbe4b020-2488-458c-a0ff-a4d83b394ef9'	(b) (4)	
User entered '1'	System	24 Aug 2020 16:02:59
	System	24 Aug 2020 16:02:59
	System	24 Aug 2020 16:02:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject stated that data was entered in error' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 18:16:05
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 'subject stated that data was entered in error' (Site from System).	Lilian Nukuna (b) (4) (b) (4)	24 Aug 2020 17:08:43
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).	System	24 Aug 2020 16:02:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-24T12:02:47', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cbe4b020-2488-458c-a0ff-a4d83b394ef9'	System	24 Aug 2020 16:02:59
User entered '1'	System	24 Aug 2020 16:02:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-24T12:02:53', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cbe4b020-2488-458c-a0ff-a4d83b394ef9'	System	24 Aug 2020 16:02:59
User entered '24 Aug 2020 12:02'	System	24 Aug 2020 16:02:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:10:47

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:10:47

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	23 Aug 2020 16:02:26
User entered 'Day 12'	System	23 Aug 2020 16:02:26

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 16:02:26

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 16:02:26

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Aug 2020 16:02:59
User entered 'Day 13'	System	24 Aug 2020 16:02:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-26T13:04:31', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9c86121d-473f-4ac5-b765-5b7b397633d1'	System	26 Aug 2020 17:05:00
User entered 'Yes (Y)'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-26T13:04:37', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9c86121d-473f-4ac5-b765-5b7b397633d1' User entered '97.7'	System	26 Aug 2020 17:05:00
	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-26T13:04:43', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9c86121d-473f-4ac5-b765-5b7b397633d1'	System	26 Aug 2020 17:05:00
User entered 'Yes (Y)'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:08:35
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 (b5e3f2ef2ab43c18)', Time: '2020-08-26T13:04:50', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9c86121d-473f-4ac5-b765-5b7b397633d1'	Erica Osmundsen (b) (4)	17 Sep 2020 22:25:49
User entered '1'	System	26 Aug 2020 17:05:00
	System	26 Aug 2020 17:05:00
	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:08:30
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:25:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-26T13:04:50', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9c86121d-473f-4ac5-b765-5b7b397633d1'	System	26 Aug 2020 17:05:00
User entered '1'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-26T13:04:56', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9c86121d-473f-4ac5-b765-5b7b397633d1'	System	26 Aug 2020 17:05:00
User entered '26 Aug 2020 13:04'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 16:02:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 16:02:59

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	26 Aug 2020 17:05:00
User entered 'Day 14'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-27T13:00:58', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '79d54fac-2c85-4357-9af8-bacbc08c0d8e'	System	27 Aug 2020 17:01:51
User entered 'Yes (Y)'	System	27 Aug 2020 17:01:51

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-27T13:01:09', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '79d54fac-2c85-4357-9af8-bacbc08c0d8e'	System	27 Aug 2020 17:01:51
User entered '97.5'	System	27 Aug 2020 17:01:51

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-27T13:01:13', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '79d54fac-2c85-4357-9af8-bacbc08c0d8e'	System	27 Aug 2020 17:01:51
User entered 'Yes (Y)'	System	27 Aug 2020 17:01:51

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:08:49
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 (b5e3f2ef2ab43c18)', Time: '2020-08-27T13:01:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '79d54fac-2c85-4357-9af8-bacbc08c0d8e'	Erica Osmundsen (b) (4)	17 Sep 2020 22:25:57
User entered '1'	System	27 Aug 2020 17:01:51

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:08:52
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:26:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-27T13:01:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '79d54fac-2c85-4357-9af8-bacbc08c0d8e'	System	27 Aug 2020 17:01:51
User entered '1'	System	27 Aug 2020 17:01:51

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-27T13:01:22', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '79d54fac-2c85-4357-9af8-bacbc08c0d8e'	System	27 Aug 2020 17:01:51
User entered '27 Aug 2020 13:01'	System	27 Aug 2020 17:01:51

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	26 Aug 2020 17:05:00
User entered 'Day 15'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-28T13:16:01', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9363e1ba-61be-4f27-b13a-4dbf6a48c8b5'	System	28 Aug 2020 18:16:27
User entered 'Yes (Y)'	System	28 Aug 2020 18:16:27

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-28T13:16:08', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9363e1ba-61be-4f27-b13a-4dbf6a48c8b5'	System	28 Aug 2020 18:16:27
User entered '97.8'	System	28 Aug 2020 18:16:27

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-28T13:16:12', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9363e1ba-61be-4f27-b13a-4dbf6a48c8b5'	System	28 Aug 2020 18:16:27
User entered 'Yes (Y)'	System	28 Aug 2020 18:16:27

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:08:59
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 (b5e3f2ef2ab43c18)', Time: '2020-08-28T13:16:15', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9363e1ba-61be-4f27-b13a-4dbf6a48c8b5'	Erica Osmundsen (b) (4)	17 Sep 2020 22:26:06
User entered '1'	System	28 Aug 2020 18:16:27

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:09:02
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:26:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-28T13:16:15', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9363e1ba-61be-4f27-b13a-4dbf6a48c8b5'	System	28 Aug 2020 18:16:27
User entered '1'	System	28 Aug 2020 18:16:27

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-28T13:16:23', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9363e1ba-61be-4f27-b13a-4dbf6a48c8b5'	System	28 Aug 2020 18:16:27
User entered '28 Aug 2020 13:16'	System	28 Aug 2020 18:16:27

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	27 Aug 2020 17:01:51
User entered 'Day 16'	System	27 Aug 2020 17:01:51

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-29T12:04:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '226beb10-167a-451e-a28d-b545e063b1ed'	System	29 Aug 2020 17:04:39
User entered 'Yes (Y)'	System	29 Aug 2020 17:04:39

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-29T12:04:22', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '226beb10-167a-451e-a28d-b545e063b1ed' User entered '98.0'	System	29 Aug 2020 17:04:39
	System	29 Aug 2020 17:04:39

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-29T12:04:25', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '226beb10-167a-451e-a28d-b545e063b1ed'	System	29 Aug 2020 17:04:39
User entered 'Yes (Y)'	System	29 Aug 2020 17:04:39

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-29T12:04:29', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '226beb10-167a-451e-a28d-b545e063b1ed' User entered '0'	System	29 Aug 2020 17:04:39
	System	29 Aug 2020 17:04:39

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:14:52
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-29T12:04:29', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '226beb10-167a-451e-a28d-b545e063b1ed'	System	29 Aug 2020 17:04:39
User entered '1'	System	29 Aug 2020 17:04:39

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-29T12:04:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '226beb10-167a-451e-a28d-b545e063b1ed' User entered '29 Aug 2020 12:04'	System	29 Aug 2020 17:04:39
	System	29 Aug 2020 17:04:39

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 17:01:51

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 17:01:51

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	28 Aug 2020 18:16:27
User entered 'Day 17'	System	28 Aug 2020 18:16:27

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-30T12:50:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '8a706d2a-bc6d-47f4-a9cf-6fddf00a201c'	System	30 Aug 2020 17:50:46
User entered 'Yes (Y)'	System	30 Aug 2020 17:50:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-30T12:50:30', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '8a706d2a-bc6d-47f4-a9cf-6fddf00a201c' User entered '97.7'	System	30 Aug 2020 17:50:46
	System	30 Aug 2020 17:50:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-30T12:50:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '8a706d2a-bc6d-47f4-a9cf-6fddf00a201c'	System	30 Aug 2020 17:50:46
User entered 'Yes (Y)'	System	30 Aug 2020 17:50:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:14:59
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 (b5e3f2ef2ab43c18)', Time: '2020-08-30T12:50:37', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '8a706d2a-bc6d-47f4-a9cf-6fddf00a201c'	Erica Osmundsen (b) (4)	17 Sep 2020 22:26:19
User entered '1'	System	30 Aug 2020 17:50:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:15:03
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:26:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-30T12:50:37', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '8a706d2a-bc6d-47f4-a9cf-6fddf00a201c'	System	30 Aug 2020 17:50:46
User entered '1'	System	30 Aug 2020 17:50:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-30T12:50:43', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '8a706d2a-bc6d-47f4-a9cf-6fddf00a201c'	System	30 Aug 2020 17:50:46
User entered '30 Aug 2020 12:50'	System	30 Aug 2020 17:50:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:16:27

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:16:27

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	29 Aug 2020 17:04:39
User entered 'Day 18'	System	29 Aug 2020 17:04:39

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-31T12:13:11', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '76f5d8f1-f62b-4fd0-a9d9-c4e55e0615e9'	System	31 Aug 2020 17:20:55
User entered 'Yes (Y)'	System	31 Aug 2020 17:20:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-31T12:13:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '76f5d8f1-f62b-4fd0-a9d9-c4e55e0615e9' User entered '97.7'	System	31 Aug 2020 17:20:55
	System	31 Aug 2020 17:20:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-31T12:13:20', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '76f5d8f1-f62b-4fd0-a9d9-c4e55e0615e9'	System	31 Aug 2020 17:20:55
User entered 'Yes (Y)'	System	31 Aug 2020 17:20:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:15:10
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 (b5e3f2ef2ab43c18)', Time: '2020-08-31T12:13:23', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '76f5d8f1-f62b-4fd0-a9d9-c4e55e0615e9'	Erica Osmundsen (b) (4)	17 Sep 2020 22:26:27
User entered '1'	System	31 Aug 2020 17:20:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:15:13
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:26:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-31T12:13:23', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '76f5d8f1-f62b-4fd0-a9d9-c4e55e0615e9'	System	31 Aug 2020 17:20:55
User entered '1'	System	31 Aug 2020 17:20:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-31T12:13:28', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '76f5d8f1-f62b-4fd0-a9d9-c4e55e0615e9'	System	31 Aug 2020 17:20:55
User entered '31 Aug 2020 12:13'	System	31 Aug 2020 17:20:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 17:04:39

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 17:04:39

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	30 Aug 2020 17:50:46
User entered 'Day 19'	System	30 Aug 2020 17:50:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-01T16:01:33', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5b7f8e50-a450-4fae-ad3a-674f809f6c7d'	System	01 Sep 2020 20:01:58
User entered 'Yes (Y)'	System	01 Sep 2020 20:01:58

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-01T16:01:39', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5b7f8e50-a450-4fae-ad3a-674f809f6c7d' User entered '97.5'	System	01 Sep 2020 20:01:58
	System	01 Sep 2020 20:01:58

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-01T16:01:43', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5b7f8e50-a450-4fae-ad3a-674f809f6c7d'	System	01 Sep 2020 20:01:58
User entered 'Yes (Y)'	System	01 Sep 2020 20:01:58

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:15:25
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:26:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-01T16:01:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5b7f8e50-a450-4fae-ad3a-674f809f6c7d'	System	01 Sep 2020 20:01:58
User entered '1'	System	01 Sep 2020 20:01:58

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:15:28
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:26:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-01T16:01:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5b7f8e50-a450-4fae-ad3a-674f809f6c7d'	System	01 Sep 2020 20:01:58
User entered '1'	System	01 Sep 2020 20:01:58

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-01T16:01:51', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5b7f8e50-a450-4fae-ad3a-674f809f6c7d'	System	01 Sep 2020 20:01:58
User entered '01 Sep 2020 16:01'	System	01 Sep 2020 20:01:58

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 17:50:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 17:50:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	31 Aug 2020 17:20:55
User entered 'Day 20'	System	31 Aug 2020 17:20:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-02T12:05:24', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7df72a57-3cc0-49b7-b1a9-ca4c6d3070f8'	System	02 Sep 2020 17:05:46
User entered 'Yes (Y)'	System	02 Sep 2020 17:05:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-02T12:05:31', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7df72a57-3cc0-49b7-b1a9-ca4c6d3070f8'	System	02 Sep 2020 17:05:46
User entered '97.5'	System	02 Sep 2020 17:05:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-02T12:05:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7df72a57-3cc0-49b7-b1a9-ca4c6d3070f8'	System	02 Sep 2020 17:05:46
User entered 'Yes (Y)'	System	02 Sep 2020 17:05:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:15:40
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 (b5e3f2ef2ab43c18)', Time: '2020-09-02T12:05:38', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7df72a57-3cc0-49b7-b1a9-ca4c6d3070f8'	Erica Osmundsen (b) (4)	17 Sep 2020 22:26:44
User entered '1'	System	02 Sep 2020 17:05:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:15:43
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:26:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-02T12:05:38', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7df72a57-3cc0-49b7-b1a9-ca4c6d3070f8'	System	02 Sep 2020 17:05:46
User entered '1'	System	02 Sep 2020 17:05:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-02T12:05:42', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7df72a57-3cc0-49b7-b1a9-ca4c6d3070f8'	System	02 Sep 2020 17:05:46
User entered '02 Sep 2020 12:05'	System	02 Sep 2020 17:05:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:20:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:20:55

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	01 Sep 2020 20:01:58
User entered 'Day 21'	System	01 Sep 2020 20:01:58

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-03T12:38:23', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fae93fe7-dade-4f07-8ff9-5e28b1f52991'	System	03 Sep 2020 17:38:46
User entered 'Yes (Y)'	System	03 Sep 2020 17:38:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-03T12:38:30', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fae93fe7-dade-4f07-8ff9-5e28b1f52991'	System	03 Sep 2020 17:38:46
User entered '97.5'	System	03 Sep 2020 17:38:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-03T12:38:33', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fae93fe7-dade-4f07-8ff9-5e28b1f52991'	System	03 Sep 2020 17:38:46
User entered 'Yes (Y)'	System	03 Sep 2020 17:38:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:15:55
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 (b5e3f2ef2ab43c18)', Time: '2020-09-03T12:38:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fae93fe7-dade-4f07-8ff9-5e28b1f52991'	Erica Osmundsen (b) (4)	17 Sep 2020 22:26:51
User entered '1'	System	03 Sep 2020 17:38:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:15:58
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:26:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-03T12:38:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fae93fe7-dade-4f07-8ff9-5e28b1f52991'	System	03 Sep 2020 17:38:46
User entered '1'	System	03 Sep 2020 17:38:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-03T12:38:41', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fae93fe7-dade-4f07-8ff9-5e28b1f52991'	System	03 Sep 2020 17:38:46
User entered '03 Sep 2020 12:38'	System	03 Sep 2020 17:38:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:01:58

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:01:58

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	02 Sep 2020 17:05:46
User entered 'Day 22'	System	02 Sep 2020 17:05:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-04T12:01:39', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c08bbfc1-7f59-41cb-a49b-8ad6edbd85d0'	System	04 Sep 2020 17:02:56
User entered 'Yes (Y)'	System	04 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-04T12:01:47', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c08bbfc1-7f59-41cb-a49b-8ad6edbd85d0'	System	04 Sep 2020 17:02:56
User entered '97.5'	System	04 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-04T12:01:51', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c08bbfc1-7f59-41cb-a49b-8ad6edbd85d0'	System	04 Sep 2020 17:02:56
User entered 'Yes (Y)'	System	04 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:16:10
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 (b5e3f2ef2ab43c18)', Time: '2020-09-04T12:01:54', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c08bbfc1-7f59-41cb-a49b-8ad6edbd85d0'	Erica Osmundsen (b) (4)	17 Sep 2020 22:27:00
User entered '1'	System	04 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:16:14
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:27:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-04T12:01:54', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c08bbfc1-7f59-41cb-a49b-8ad6edbd85d0'	System	04 Sep 2020 17:02:56
User entered '1'	System	04 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-04T12:01:58', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c08bbfc1-7f59-41cb-a49b-8ad6edbd85d0'	System	04 Sep 2020 17:02:56
User entered '04 Sep 2020 12:01'	System	04 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:05:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:05:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	03 Sep 2020 17:38:46
User entered 'Day 23'	System	03 Sep 2020 17:38:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-05T12:00:51', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '882b5f77-9712-4e07-a01d-d71ae4889385'	System	05 Sep 2020 17:01:21
User entered 'Yes (Y)'	System	05 Sep 2020 17:01:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-05T12:00:57', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '882b5f77-9712-4e07-a01d-d71ae4889385' User entered '97.5'	System	05 Sep 2020 17:01:21
	System	05 Sep 2020 17:01:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-05T12:01:01', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '882b5f77-9712-4e07-a01d-d71ae4889385'	System	05 Sep 2020 17:01:21
User entered 'Yes (Y)'	System	05 Sep 2020 17:01:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:16:27
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:27:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-05T12:01:05', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '882b5f77-9712-4e07-a01d-d71ae4889385'	System	05 Sep 2020 17:01:21
User entered '1'	System	05 Sep 2020 17:01:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:16:30
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:27:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-05T12:01:05', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '882b5f77-9712-4e07-a01d-d71ae4889385'	System	05 Sep 2020 17:01:21
User entered '1'	System	05 Sep 2020 17:01:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-05T12:01:09', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '882b5f77-9712-4e07-a01d-d71ae4889385'	System	05 Sep 2020 17:01:21
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 17:01:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:38:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:38:46

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	04 Sep 2020 17:02:56
User entered 'Day 24'	System	04 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-06T12:03:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6ee5d31b-d8fb-4b1b-ac6f-0a02d52a4a4a'	System	06 Sep 2020 17:03:50
User entered 'Yes (Y)'	System	06 Sep 2020 17:03:50

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-06T12:03:33', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6ee5d31b-d8fb-4b1b-ac6f-0a02d52a4a4a' User entered '97.5'	System	06 Sep 2020 17:03:50
	System	06 Sep 2020 17:03:50

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-06T12:03:37', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6ee5d31b-d8fb-4b1b-ac6f-0a02d52a4a4a'	System	06 Sep 2020 17:03:50
User entered 'Yes (Y)'	System	06 Sep 2020 17:03:50

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:16:36
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:27:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-06T12:03:39', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6ee5d31b-d8fb-4b1b-ac6f-0a02d52a4a4a'	System	06 Sep 2020 17:03:50
User entered '1'	System	06 Sep 2020 17:03:50

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:16:40
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:27:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-06T12:03:39', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6ee5d31b-d8fb-4b1b-ac6f-0a02d52a4a4a'	System	06 Sep 2020 17:03:50
User entered '1'	System	06 Sep 2020 17:03:50

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-06T12:03:43', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6ee5d31b-d8fb-4b1b-ac6f-0a02d52a4a4a'	System	06 Sep 2020 17:03:50
User entered '06 Sep 2020 12:03'	System	06 Sep 2020 17:03:50

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	05 Sep 2020 17:01:21
User entered 'Day 25'	System	05 Sep 2020 17:01:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-07T12:12:14', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3b5ba90e-8443-4205-8447-31a8db6ef5bb'	System	07 Sep 2020 17:12:38
User entered 'Yes (Y)'	System	07 Sep 2020 17:12:38

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-07T12:12:19', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3b5ba90e-8443-4205-8447-31a8db6ef5bb'	System	07 Sep 2020 17:12:38
User entered '97.5'	System	07 Sep 2020 17:12:38

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-07T12:12:25', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3b5ba90e-8443-4205-8447-31a8db6ef5bb'	System	07 Sep 2020 17:12:38
User entered 'Yes (Y)'	System	07 Sep 2020 17:12:38

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:17:39
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 (b5e3f2ef2ab43c18)', Time: '2020-09-07T12:12:29', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3b5ba90e-8443-4205-8447-31a8db6ef5bb'	Erica Osmundsen (b) (4)	17 Sep 2020 22:27:30
User entered '1'	System	07 Sep 2020 17:12:38

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-07T12:12:29', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3b5ba90e-8443-4205-8447-31a8db6ef5bb'	System	07 Sep 2020 17:12:38
User entered '0'	System	07 Sep 2020 17:12:38

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-07T12:12:33', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3b5ba90e-8443-4205-8447-31a8db6ef5bb'	System	07 Sep 2020 17:12:38
User entered '07 Sep 2020 12:12'	System	07 Sep 2020 17:12:38

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:01:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:01:21

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	06 Sep 2020 17:03:50
User entered 'Day 26'	System	06 Sep 2020 17:03:50

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-08T13:01:03', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '193476cb-3552-414e-bc20-b2fda9cd9426'	System	08 Sep 2020 17:02:24
User entered 'Yes (Y)'	System	08 Sep 2020 17:02:24

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-08T13:01:10', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '193476cb-3552-414e-bc20-b2fda9cd9426'	System	08 Sep 2020 17:02:24
User entered '97.5'	System	08 Sep 2020 17:02:24

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-08T13:01:13', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '193476cb-3552-414e-bc20-b2fda9cd9426'	System	08 Sep 2020 17:02:24
User entered 'Yes (Y)'	System	08 Sep 2020 17:02:24

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:17:51
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:27:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-08T13:01:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '193476cb-3552-414e-bc20-b2fda9cd9426'	System	08 Sep 2020 17:02:24
User entered '1'	System	08 Sep 2020 17:02:24

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 15:41:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
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 'subject confirmed this entry refers only to daily pain meds taken for chronic pain and ongoing at start of study--no new medication and no new symptoms' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 17:17:54
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).	Erica Osmundsen (b) (4)	17 Sep 2020 22:27:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-08T13:01:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '193476cb-3552-414e-bc20-b2fda9cd9426'	System	08 Sep 2020 17:02:24
User entered '1'	System	08 Sep 2020 17:02:24

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-08T13:01:21', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '193476cb-3552-414e-bc20-b2fda9cd9426'	System	08 Sep 2020 17:02:24
User entered '08 Sep 2020 13:01'	System	08 Sep 2020 17:02:24

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 17:03:50

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 17:03:50

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	07 Sep 2020 17:12:38
User entered 'Day 27'	System	07 Sep 2020 17:12:38

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-09T13:21:55', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '49ea9d89-73f2-474d-9bb1-71bb64a0a9f8'	System	09 Sep 2020 17:22:12
User entered 'Yes (Y)'	System	09 Sep 2020 17:22:12

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-09T13:22:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '49ea9d89-73f2-474d-9bb1-71bb64a0a9f8'	System	09 Sep 2020 17:22:12
User entered '97.7'	System	09 Sep 2020 17:22:12

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-09T13:22:03', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '49ea9d89-73f2-474d-9bb1-71bb64a0a9f8'	System	09 Sep 2020 17:22:12
User entered 'No (N)'	System	09 Sep 2020 17:22:12

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-09T13:22:07', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '49ea9d89-73f2-474d-9bb1-71bb64a0a9f8'	System	09 Sep 2020 17:22:12
User entered '09 Sep 2020 13:22'	System	09 Sep 2020 17:22:12

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 17:12:38

US3202191

Folder: Diary Dose 1 (1)

Form: Temperature_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 17:12:38

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:13:10', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'd18f66b3-d16e-4831-9314-8c0b3741fce2'	System	14 Aug 2020 18:15:55
User entered 'None (1)'	System	14 Aug 2020 18:15:55

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:13:16', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'd18f66b3-d16e-4831-9314-8c0b3741fce2'	System	14 Aug 2020 18:15:55
User entered 'No (N)'	System	14 Aug 2020 18:15:55

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:13:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'd18f66b3-d16e-4831-9314-8c0b3741fce2'	System	14 Aug 2020 18:15:55
User entered 'No (N)'	System	14 Aug 2020 18:15:55

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:13:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'd18f66b3-d16e-4831-9314-8c0b3741fce2'	System	14 Aug 2020 18:15:55
User entered 'None (1)'	System	14 Aug 2020 18:15:55

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:13:54', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'd18f66b3-d16e-4831-9314-8c0b3741fce2'	System	14 Aug 2020 18:15:55
User entered '14 Aug 2020 14:13'	System	14 Aug 2020 18:15:55

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Aug 2020 13:39'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Aug 2020 16:09'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:11:15', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'aa19cf3d-6f56-470d-a02f-cee2c73d4a47'	System	14 Aug 2020 21:12:04
User entered 'None (1)'	System	14 Aug 2020 21:12:04

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:11:23', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'aa19cf3d-6f56-470d-a02f-cee2c73d4a47'	System	14 Aug 2020 21:12:04
User entered 'No (N)'	System	14 Aug 2020 21:12:04

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:11:38', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'aa19cf3d-6f56-470d-a02f-cee2c73d4a47'	System	14 Aug 2020 21:12:04
User entered 'No (N)'	System	14 Aug 2020 21:12:04

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:11:48', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'aa19cf3d-6f56-470d-a02f-cee2c73d4a47'	System	14 Aug 2020 21:12:04
User entered 'None (1)'	System	14 Aug 2020 21:12:04

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:12:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'aa19cf3d-6f56-470d-a02f-cee2c73d4a47'	System	14 Aug 2020 21:12:04
User entered '14 Aug 2020 17:12'	System	14 Aug 2020 21:12:04

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Aug 2020 17:04'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 2'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:17:09', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a882d8d5-9a93-498f-8f37-a29767843614'	System	15 Aug 2020 17:17:52
User entered 'None (1)'	System	15 Aug 2020 17:17:52

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:17:19', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a882d8d5-9a93-498f-8f37-a29767843614'	System	15 Aug 2020 17:17:52
User entered 'No (N)'	System	15 Aug 2020 17:17:52

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:17:28', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a882d8d5-9a93-498f-8f37-a29767843614'	System	15 Aug 2020 17:17:52
User entered 'No (N)'	System	15 Aug 2020 17:17:52

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:17:40', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a882d8d5-9a93-498f-8f37-a29767843614'	System	15 Aug 2020 17:17:52
User entered 'None (1)'	System	15 Aug 2020 17:17:52

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:17:47', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a882d8d5-9a93-498f-8f37-a29767843614'	System	15 Aug 2020 17:17:52
User entered '15 Aug 2020 12:17'	System	15 Aug 2020 17:17:52

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 3'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:11:02', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fb5dc8d1-13d5-4206-b1b0-e8df92801aa1'	System	16 Aug 2020 17:11:30
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 17:11:30

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:11:06', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fb5dc8d1-13d5-4206-b1b0-e8df92801aa1'	System	16 Aug 2020 17:11:30
User entered 'No (N)'	System	16 Aug 2020 17:11:30

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:11:11', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fb5dc8d1-13d5-4206-b1b0-e8df92801aa1'	System	16 Aug 2020 17:11:30
User entered 'No (N)'	System	16 Aug 2020 17:11:30

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:11:21', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fb5dc8d1-13d5-4206-b1b0-e8df92801aa1'	System	16 Aug 2020 17:11:30
User entered 'None (1)'	System	16 Aug 2020 17:11:30

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:11:28', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fb5dc8d1-13d5-4206-b1b0-e8df92801aa1'	System	16 Aug 2020 17:11:30
User entered '16 Aug 2020 12:11'	System	16 Aug 2020 17:11:30

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 4'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:31:15', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c67021a0-e266-4b21-a47c-ce3aa0178d66'	System	17 Aug 2020 17:31:42
User entered 'None (1)'	System	17 Aug 2020 17:31:42

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:31:20', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c67021a0-e266-4b21-a47c-ce3aa0178d66'	System	17 Aug 2020 17:31:42
User entered 'No (N)'	System	17 Aug 2020 17:31:42

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:31:24', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c67021a0-e266-4b21-a47c-ce3aa0178d66'	System	17 Aug 2020 17:31:42
User entered 'No (N)'	System	17 Aug 2020 17:31:42

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:31:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c67021a0-e266-4b21-a47c-ce3aa0178d66'	System	17 Aug 2020 17:31:42
User entered 'None (1)'	System	17 Aug 2020 17:31:42

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:31:40', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c67021a0-e266-4b21-a47c-ce3aa0178d66'	System	17 Aug 2020 17:31:42
User entered '17 Aug 2020 12:31'	System	17 Aug 2020 17:31:42

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 5'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:09:02', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'baef7110-7657-4a5f-a285-1b296cb9d6dc'	System	18 Aug 2020 17:10:43
User entered 'None (1)'	System	18 Aug 2020 17:10:43

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:09:21', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'baef7110-7657-4a5f-a285-1b296cb9d6dc'	System	18 Aug 2020 17:10:43
User entered 'No (N)'	System	18 Aug 2020 17:10:43

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:10:28', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'baef7110-7657-4a5f-a285-1b296cb9d6dc'	System	18 Aug 2020 17:10:43
User entered 'No (N)'	System	18 Aug 2020 17:10:43

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:10:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'baef7110-7657-4a5f-a285-1b296cb9d6dc'	System	18 Aug 2020 17:10:43
User entered 'None (1)'	System	18 Aug 2020 17:10:43

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:10:42', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'baef7110-7657-4a5f-a285-1b296cb9d6dc'	System	18 Aug 2020 17:10:43
User entered '18 Aug 2020 12:10'	System	18 Aug 2020 17:10:43

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 6'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:19:24', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'caff25cf-dbbf-40d5-98c3-3e0aa27accf6'	System	19 Aug 2020 17:19:45
User entered 'None (1)'	System	19 Aug 2020 17:19:45

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:19:27', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'caff25cf-dbbf-40d5-98c3-3e0aa27accf6'	System	19 Aug 2020 17:19:45
User entered 'No (N)'	System	19 Aug 2020 17:19:45

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:19:31', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'caff25cf-dbbf-40d5-98c3-3e0aa27accf6'	System	19 Aug 2020 17:19:45
User entered 'No (N)'	System	19 Aug 2020 17:19:45

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:19:37', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'caff25cf-dbbf-40d5-98c3-3e0aa27accf6'	System	19 Aug 2020 17:19:45
User entered 'None (1)'	System	19 Aug 2020 17:19:45

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:19:43', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'caff25cf-dbbf-40d5-98c3-3e0aa27accf6'	System	19 Aug 2020 17:19:45
User entered '19 Aug 2020 12:19'	System	19 Aug 2020 17:19:45

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 7'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:36:27', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9054bbd4-eed7-4c35-a4e2-d03f969055bc'	System	20 Aug 2020 18:36:46
User entered 'None (1)'	System	20 Aug 2020 18:36:46

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:36:30', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9054bbd4-eed7-4c35-a4e2-d03f969055bc'	System	20 Aug 2020 18:36:46
User entered 'No (N)'	System	20 Aug 2020 18:36:46

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:36:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9054bbd4-eed7-4c35-a4e2-d03f969055bc'	System	20 Aug 2020 18:36:46
User entered 'No (N)'	System	20 Aug 2020 18:36:46

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:36:37', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9054bbd4-eed7-4c35-a4e2-d03f969055bc'	System	20 Aug 2020 18:36:46
User entered 'None (1)'	System	20 Aug 2020 18:36:46

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:36:44', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9054bbd4-eed7-4c35-a4e2-d03f969055bc'	System	20 Aug 2020 18:36:46
User entered '20 Aug 2020 14:36'	System	20 Aug 2020 18:36:46

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:14:04', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6f3d1b6b-b0e1-4f1b-b896-d7c14b875c8d'	System	14 Aug 2020 18:15:48
User entered 'None (0)'	System	14 Aug 2020 18:15:48

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:14:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6f3d1b6b-b0e1-4f1b-b896-d7c14b875c8d'	System	14 Aug 2020 18:15:48
User entered 'None (0)'	System	14 Aug 2020 18:15:48

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:14:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6f3d1b6b-b0e1-4f1b-b896-d7c14b875c8d'	System	14 Aug 2020 18:15:48
User entered 'None (0)'	System	14 Aug 2020 18:15:48

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:14:39', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6f3d1b6b-b0e1-4f1b-b896-d7c14b875c8d'	System	14 Aug 2020 18:15:48
User entered 'None (0)'	System	14 Aug 2020 18:15:48

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:14:43', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6f3d1b6b-b0e1-4f1b-b896-d7c14b875c8d'	System	14 Aug 2020 18:15:48
User entered 'None (0)'	System	14 Aug 2020 18:15:48

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:14:47', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6f3d1b6b-b0e1-4f1b-b896-d7c14b875c8d'	System	14 Aug 2020 18:15:48
User entered 'None (0)'	System	14 Aug 2020 18:15:48

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:14:53', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6f3d1b6b-b0e1-4f1b-b896-d7c14b875c8d'	System	14 Aug 2020 18:15:48
User entered 'No (N)'	System	14 Aug 2020 18:15:48

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T14:15:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6f3d1b6b-b0e1-4f1b-b896-d7c14b875c8d'	System	14 Aug 2020 18:15:48
User entered '14 Aug 2020 14:15'	System	14 Aug 2020 18:15:48

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Aug 2020 13:39'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Aug 2020 16:09'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:12:08', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '81211503-00ef-4e6f-9da4-dd01efb3a7e4'	System	14 Aug 2020 21:13:39
User entered 'None (0)'	System	14 Aug 2020 21:13:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:12:20', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '81211503-00ef-4e6f-9da4-dd01efb3a7e4'	System	14 Aug 2020 21:13:39
User entered 'None (0)'	System	14 Aug 2020 21:13:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:12:33', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '81211503-00ef-4e6f-9da4-dd01efb3a7e4'	System	14 Aug 2020 21:13:39
User entered 'No interference with activity (1)'	System	14 Aug 2020 21:13:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:12:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '81211503-00ef-4e6f-9da4-dd01efb3a7e4'	System	14 Aug 2020 21:13:39
User entered 'No interference with activity (1)'	System	14 Aug 2020 21:13:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:12:50', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '81211503-00ef-4e6f-9da4-dd01efb3a7e4'	System	14 Aug 2020 21:13:39
User entered 'None (0)'	System	14 Aug 2020 21:13:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:12:54', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '81211503-00ef-4e6f-9da4-dd01efb3a7e4'	System	14 Aug 2020 21:13:39
User entered 'None (0)'	System	14 Aug 2020 21:13:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:13:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '81211503-00ef-4e6f-9da4-dd01efb3a7e4'	System	14 Aug 2020 21:13:39
User entered 'No (N)'	System	14 Aug 2020 21:13:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-14T17:13:10', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '81211503-00ef-4e6f-9da4-dd01efb3a7e4'	System	14 Aug 2020 21:13:39
User entered '14 Aug 2020 17:13'	System	14 Aug 2020 21:13:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Aug 2020 17:04'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 2'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:17:54', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e7280fce-6ed2-456d-84bb-4698df27794e'	System	15 Aug 2020 17:18:39
User entered 'None (0)'	System	15 Aug 2020 17:18:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:18:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e7280fce-6ed2-456d-84bb-4698df27794e'	System	15 Aug 2020 17:18:39
User entered 'No interference with activity (1)'	System	15 Aug 2020 17:18:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:18:08', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e7280fce-6ed2-456d-84bb-4698df27794e'	System	15 Aug 2020 17:18:39
User entered 'No interference with activity (1)'	System	15 Aug 2020 17:18:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:18:15', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e7280fce-6ed2-456d-84bb-4698df27794e'	System	15 Aug 2020 17:18:39
User entered 'No interference with activity (1)'	System	15 Aug 2020 17:18:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:18:19', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e7280fce-6ed2-456d-84bb-4698df27794e'	System	15 Aug 2020 17:18:39
User entered 'None (0)'	System	15 Aug 2020 17:18:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:18:22', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e7280fce-6ed2-456d-84bb-4698df27794e'	System	15 Aug 2020 17:18:39
User entered 'None (0)'	System	15 Aug 2020 17:18:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:18:28', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e7280fce-6ed2-456d-84bb-4698df27794e'	System	15 Aug 2020 17:18:39
User entered 'No (N)'	System	15 Aug 2020 17:18:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-15T12:18:37', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e7280fce-6ed2-456d-84bb-4698df27794e'	System	15 Aug 2020 17:18:39
User entered '15 Aug 2020 12:18'	System	15 Aug 2020 17:18:39

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 3'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:11:42', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '72f18b3b-0a7a-45b6-b481-5b32394b8334'	System	16 Aug 2020 17:12:25
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		16 Aug 2020 17:12:25

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:11:49', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '72f18b3b-0a7a-45b6-b481-5b32394b8334'	System	16 Aug 2020 17:12:25
User entered 'Some interference with activity (2)'	System	16 Aug 2020 17:12:25

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:11:54', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '72f18b3b-0a7a-45b6-b481-5b32394b8334'	System	16 Aug 2020 17:12:25
User entered 'No interference with activity (1)'	System	16 Aug 2020 17:12:25

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:12:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '72f18b3b-0a7a-45b6-b481-5b32394b8334'	System	16 Aug 2020 17:12:25
User entered 'Some interference with activity (2)'	System	16 Aug 2020 17:12:25

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:12:03', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '72f18b3b-0a7a-45b6-b481-5b32394b8334'	System	16 Aug 2020 17:12:25
User entered 'None (0)'	System	16 Aug 2020 17:12:25

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:12:08', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '72f18b3b-0a7a-45b6-b481-5b32394b8334'	System	16 Aug 2020 17:12:25
User entered 'None (0)'	System	16 Aug 2020 17:12:25

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:12:13', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '72f18b3b-0a7a-45b6-b481-5b32394b8334'	System	16 Aug 2020 17:12:25
User entered 'No (N)'	System	16 Aug 2020 17:12:25

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-16T12:12:21', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '72f18b3b-0a7a-45b6-b481-5b32394b8334'	System	16 Aug 2020 17:12:25
User entered '16 Aug 2020 12:12'	System	16 Aug 2020 17:12:25

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 4'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:31:48', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '01a50be0-2e54-42ec-8982-0498cda1f684'	System	17 Aug 2020 17:32:22
User entered 'None (0)'	System	17 Aug 2020 17:32:22

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:31:52', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '01a50be0-2e54-42ec-8982-0498cda1f684'	System	17 Aug 2020 17:32:22
User entered 'No interference with activity (1)'	System	17 Aug 2020 17:32:22

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:31:55', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '01a50be0-2e54-42ec-8982-0498cda1f684'	System	17 Aug 2020 17:32:22
User entered 'No interference with activity (1)'	System	17 Aug 2020 17:32:22

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:32:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '01a50be0-2e54-42ec-8982-0498cda1f684'	System	17 Aug 2020 17:32:22
User entered 'Some interference with activity (2)'	System	17 Aug 2020 17:32:22

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:32:04', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '01a50be0-2e54-42ec-8982-0498cda1f684'	System	17 Aug 2020 17:32:22
User entered 'None (0)'	System	17 Aug 2020 17:32:22

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:32:07', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '01a50be0-2e54-42ec-8982-0498cda1f684'	System	17 Aug 2020 17:32:22
User entered 'None (0)'	System	17 Aug 2020 17:32:22

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:32:15', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '01a50be0-2e54-42ec-8982-0498cda1f684'	System	17 Aug 2020 17:32:22
User entered 'No (N)'	System	17 Aug 2020 17:32:22

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-17T12:32:20', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '01a50be0-2e54-42ec-8982-0498cda1f684'	System	17 Aug 2020 17:32:22
User entered '17 Aug 2020 12:32'	System	17 Aug 2020 17:32:22

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 5'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:10:49', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9b6f988b-f264-4d7d-9389-d1edd9480bac'	System	18 Aug 2020 17:11:23
User entered 'No interference with activity (1)'	System	18 Aug 2020 17:11:23

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:10:52', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9b6f988b-f264-4d7d-9389-d1edd9480bac'	System	18 Aug 2020 17:11:23
User entered 'No interference with activity (1)'	System	18 Aug 2020 17:11:23

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:10:57', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9b6f988b-f264-4d7d-9389-d1edd9480bac'	System	18 Aug 2020 17:11:23
User entered 'Some interference with activity (2)'	System	18 Aug 2020 17:11:23

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:11:01', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9b6f988b-f264-4d7d-9389-d1edd9480bac'	System	18 Aug 2020 17:11:23
User entered 'Some interference with activity (2)'	System	18 Aug 2020 17:11:23

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:11:04', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9b6f988b-f264-4d7d-9389-d1edd9480bac'	System	18 Aug 2020 17:11:23
User entered 'None (0)'	System	18 Aug 2020 17:11:23

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:11:07', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9b6f988b-f264-4d7d-9389-d1edd9480bac'	System	18 Aug 2020 17:11:23
User entered 'None (0)'	System	18 Aug 2020 17:11:23

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:11:14', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9b6f988b-f264-4d7d-9389-d1edd9480bac'	System	18 Aug 2020 17:11:23
User entered 'No (N)'	System	18 Aug 2020 17:11:23

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-18T12:11:21', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9b6f988b-f264-4d7d-9389-d1edd9480bac'	System	18 Aug 2020 17:11:23
User entered '18 Aug 2020 12:11'	System	18 Aug 2020 17:11:23

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 6'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:19:49', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b3674ffa-6276-4468-aad1-9302c37de469'	System	19 Aug 2020 17:20:29
User entered 'No interference with activity (1)'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:19:52', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b3674ffa-6276-4468-aad1-9302c37de469'	System	19 Aug 2020 17:20:29
User entered 'No interference with activity (1)'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:19:58', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b3674ffa-6276-4468-aad1-9302c37de469'	System	19 Aug 2020 17:20:29
User entered 'Some interference with activity (2)'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:20:01', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b3674ffa-6276-4468-aad1-9302c37de469'	System	19 Aug 2020 17:20:29
User entered 'Some interference with activity (2)'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:20:04', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b3674ffa-6276-4468-aad1-9302c37de469'	System	19 Aug 2020 17:20:29
User entered 'None (0)'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:20:07', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b3674ffa-6276-4468-aad1-9302c37de469'	System	19 Aug 2020 17:20:29
User entered 'None (0)'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:20:21', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b3674ffa-6276-4468-aad1-9302c37de469'	System	19 Aug 2020 17:20:29
User entered 'No (N)'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-19T12:20:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b3674ffa-6276-4468-aad1-9302c37de469'	System	19 Aug 2020 17:20:29
User entered '19 Aug 2020 12:20'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 7'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:36:53', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '39571ecb-a0bb-491b-ac26-1d3689132221'	System	20 Aug 2020 18:37:35
User entered 'None (0)'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:36:57', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '39571ecb-a0bb-491b-ac26-1d3689132221'	System	20 Aug 2020 18:37:35
User entered 'No interference with activity (1)'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:37:07', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '39571ecb-a0bb-491b-ac26-1d3689132221'	System	20 Aug 2020 18:37:35
User entered 'Some interference with activity (2)'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:37:11', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '39571ecb-a0bb-491b-ac26-1d3689132221'	System	20 Aug 2020 18:37:35
User entered 'Some interference with activity (2)'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:37:14', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '39571ecb-a0bb-491b-ac26-1d3689132221'	System	20 Aug 2020 18:37:35
User entered 'None (0)'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:37:16', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '39571ecb-a0bb-491b-ac26-1d3689132221'	System	20 Aug 2020 18:37:35
User entered 'None (0)'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:37:27', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '39571ecb-a0bb-491b-ac26-1d3689132221'	System	20 Aug 2020 18:37:35
User entered 'No (N)'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-20T14:37:32', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '39571ecb-a0bb-491b-ac26-1d3689132221'	System	20 Aug 2020 18:37:35
User entered '20 Aug 2020 14:37'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	19 Aug 2020 17:20:29
User entered 'Day 8'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-21T12:03:20', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b0511d43-7b6b-4ffc-b2cb-e6abaa054b1c'	System	21 Aug 2020 16:03:30
User entered 'Some interference with activity (2)'	System	21 Aug 2020 16:03:30

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-21T12:03:24', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b0511d43-7b6b-4ffc-b2cb-e6abaa054b1c'	System	21 Aug 2020 16:03:30
User entered '21 Aug 2020 12:03'	System	21 Aug 2020 16:03:30

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	20 Aug 2020 18:37:35
User entered 'Day 9'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-22T13:10:47', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '12363846-8e15-4b2a-88ec-3186fb03d4ef'	System	22 Aug 2020 17:10:57
User entered 'No interference with activity (1)'	System	22 Aug 2020 17:10:57

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-22T13:10:54', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '12363846-8e15-4b2a-88ec-3186fb03d4ef'	System	22 Aug 2020 17:10:57
User entered '22 Aug 2020 13:10'	System	22 Aug 2020 17:10:57

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	21 Aug 2020 16:03:30
User entered 'Day 10'	System	21 Aug 2020 16:03:30

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-23T12:02:29', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '068292d3-7b16-4023-89ab-606ce373f809'	System	23 Aug 2020 16:02:38
User entered 'No interference with activity (1)'	System	23 Aug 2020 16:02:38

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-23T12:02:33', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '068292d3-7b16-4023-89ab-606ce373f809'	System	23 Aug 2020 16:02:38
User entered '23 Aug 2020 12:02'	System	23 Aug 2020 16:02:38

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:03:30

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:03:30

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	22 Aug 2020 17:10:57
User entered 'Day 11'	System	22 Aug 2020 17:10:57

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-24T12:03:03', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1741d1d2-36c7-4fdd-894e-73e04140b149'	System	24 Aug 2020 16:03:11
User entered 'No interference with activity (1)'	System	24 Aug 2020 16:03:11

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-24T12:03:05', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1741d1d2-36c7-4fdd-894e-73e04140b149'	System	24 Aug 2020 16:03:11
User entered '24 Aug 2020 12:03'	System	24 Aug 2020 16:03:11

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:10:57

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:10:57

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	23 Aug 2020 16:02:38
User entered 'Day 12'	System	23 Aug 2020 16:02:38

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 16:02:38

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 16:02:38

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Aug 2020 16:03:11
User entered 'Day 13'	System	24 Aug 2020 16:03:11

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-26T13:05:03', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ca7605b2-0e62-43fc-ae69-b18719512b6b'	System	26 Aug 2020 17:05:10
User entered 'Some interference with activity (2)'	System	26 Aug 2020 17:05:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-26T13:05:07', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ca7605b2-0e62-43fc-ae69-b18719512b6b'	System	26 Aug 2020 17:05:10
User entered '26 Aug 2020 13:05'	System	26 Aug 2020 17:05:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 16:03:11

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 16:03:11

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	26 Aug 2020 17:05:10
User entered 'Day 14'	System	26 Aug 2020 17:05:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-27T13:01:31', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '2b6350d6-3c7e-460f-98f3-16166d4bae54'	System	27 Aug 2020 17:02:10
User entered 'No interference with activity (1)'	System	27 Aug 2020 17:02:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-27T13:01:35', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '2b6350d6-3c7e-460f-98f3-16166d4bae54'	System	27 Aug 2020 17:02:10
User entered '27 Aug 2020 13:01'	System	27 Aug 2020 17:02:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:05:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:05:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	26 Aug 2020 17:05:10
User entered 'Day 15'	System	26 Aug 2020 17:05:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-28T13:16:27', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '0883c289-bf3c-4f19-9371-550748b98059'	System	28 Aug 2020 18:16:35
User entered 'Some interference with activity (2)'	System	28 Aug 2020 18:16:35

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-28T13:16:31', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '0883c289-bf3c-4f19-9371-550748b98059'	System	28 Aug 2020 18:16:35
User entered '28 Aug 2020 13:16'	System	28 Aug 2020 18:16:35

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:05:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:05:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	27 Aug 2020 17:02:10
User entered 'Day 16'	System	27 Aug 2020 17:02:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-29T12:04:40', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fb7a12ed-b3ae-439f-bf80-3a000836d4ac'	System	29 Aug 2020 17:04:46
User entered 'Some interference with activity (2)'	System	29 Aug 2020 17:04:46

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-29T12:04:43', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fb7a12ed-b3ae-439f-bf80-3a000836d4ac'	System	29 Aug 2020 17:04:46
User entered '29 Aug 2020 12:04'	System	29 Aug 2020 17:04:46

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 17:02:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 17:02:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	28 Aug 2020 18:16:35
User entered 'Day 17'	System	28 Aug 2020 18:16:35

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-30T12:50:52', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1fbc9bb-8381-4bf8-bf52-47f218a2730d'	System	30 Aug 2020 17:50:57
User entered 'Some interference with activity (2)'	System	30 Aug 2020 17:50:57

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-30T12:50:55', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1fbc9bb-8381-4bf8-bf52-47f218a2730d'	System	30 Aug 2020 17:50:57
User entered '30 Aug 2020 12:50'	System	30 Aug 2020 17:50:57

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:16:35

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:16:35

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	29 Aug 2020 17:04:46
User entered 'Day 18'	System	29 Aug 2020 17:04:46

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-31T12:13:35', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '2537782d-edf4-44d9-a4f6-b5a3b599c4e9'	System	31 Aug 2020 17:20:58
User entered 'Some interference with activity (2)'	System	31 Aug 2020 17:20:58

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-31T12:13:38', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '2537782d-edf4-44d9-a4f6-b5a3b599c4e9'	System	31 Aug 2020 17:20:58
User entered '31 Aug 2020 12:13'	System	31 Aug 2020 17:20:58

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 17:04:46

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 17:04:46

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	30 Aug 2020 17:50:57
User entered 'Day 19'	System	30 Aug 2020 17:50:57

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-01T16:01:57', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '96238a4f-3c90-4749-8bcc-a4b179172ebb'	System	01 Sep 2020 20:02:04
User entered 'No interference with activity (1)'	System	01 Sep 2020 20:02:04

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-01T16:02:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '96238a4f-3c90-4749-8bcc-a4b179172ebb'	System	01 Sep 2020 20:02:04
User entered '01 Sep 2020 16:02'	System	01 Sep 2020 20:02:04

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 17:50:57

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 17:50:57

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	31 Aug 2020 17:20:58
User entered 'Day 20'	System	31 Aug 2020 17:20:58

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-02T12:05:48', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '998eee5b-fcd4-41f4-b7f1-bf1da387f1ad'	System	02 Sep 2020 17:05:54
User entered 'Some interference with activity (2)'	System	02 Sep 2020 17:05:54

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-02T12:05:51', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '998eee5b-fcd4-41f4-b7f1-bf1da387f1ad'	System	02 Sep 2020 17:05:54
User entered '02 Sep 2020 12:05'	System	02 Sep 2020 17:05:54

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:20:58

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:20:58

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	01 Sep 2020 20:02:04
User entered 'Day 21'	System	01 Sep 2020 20:02:04

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-03T12:38:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ec593359-c7df-4046-91ca-a00f29a2f396'	System	03 Sep 2020 17:38:55
User entered 'Some interference with activity (2)'	System	03 Sep 2020 17:38:55

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-03T12:38:52', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ec593359-c7df-4046-91ca-a00f29a2f396'	System	03 Sep 2020 17:38:55
User entered '03 Sep 2020 12:38'	System	03 Sep 2020 17:38:55

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:02:04

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:02:04

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	02 Sep 2020 17:05:54
User entered 'Day 22'	System	02 Sep 2020 17:05:54

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-04T12:02:02', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b7f2476a-2ba4-4c10-80c4-940a02aeaca6'	System	04 Sep 2020 17:03:05
User entered 'Some interference with activity (2)'	System	04 Sep 2020 17:03:05

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-04T12:02:05', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b7f2476a-2ba4-4c10-80c4-940a02aeaca6'	System	04 Sep 2020 17:03:05
User entered '04 Sep 2020 12:02'	System	04 Sep 2020 17:03:05

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:05:54

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:05:54

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	03 Sep 2020 17:38:55
User entered 'Day 23'	System	03 Sep 2020 17:38:55

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-05T12:01:13', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b38fb96c-7ba6-4808-b160-124d14f2c79e'	System	05 Sep 2020 17:01:30
User entered 'Some interference with activity (2)'	System	05 Sep 2020 17:01:30

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-05T12:01:16', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b38fb96c-7ba6-4808-b160-124d14f2c79e'	System	05 Sep 2020 17:01:30
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 17:01:30

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:38:55

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:38:55

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	04 Sep 2020 17:03:05
User entered 'Day 24'	System	04 Sep 2020 17:03:05

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-06T12:03:47', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '672fdfc8-fc2f-48d6-a876-42dfdadd3413'	System	06 Sep 2020 17:03:55
User entered 'Some interference with activity (2)'	System	06 Sep 2020 17:03:55

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-06T12:03:50', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '672fdfc8-fc2f-48d6-a876-42dfdadd3413'	System	06 Sep 2020 17:03:55
User entered '06 Sep 2020 12:03'	System	06 Sep 2020 17:03:55

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 17:03:05

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 17:03:05

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	05 Sep 2020 17:01:30
User entered 'Day 25'	System	05 Sep 2020 17:01:30

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-07T12:12:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '934e8e61-5410-479d-8ad6-11f5d64b7d18'	System	07 Sep 2020 17:12:42
User entered 'Some interference with activity (2)'	System	07 Sep 2020 17:12:42

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-07T12:12:39', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '934e8e61-5410-479d-8ad6-11f5d64b7d18'	System	07 Sep 2020 17:12:42
User entered '07 Sep 2020 12:12'	System	07 Sep 2020 17:12:42

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:01:30

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:01:30

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	06 Sep 2020 17:03:55
User entered 'Day 26'	System	06 Sep 2020 17:03:55

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-08T13:01:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9e62eee6-e73f-4faa-8af3-45ec700a1e13'	System	08 Sep 2020 17:02:40
User entered 'Some interference with activity (2)'	System	08 Sep 2020 17:02:40

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-08T13:01:29', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9e62eee6-e73f-4faa-8af3-45ec700a1e13'	System	08 Sep 2020 17:02:40
User entered '08 Sep 2020 13:01'	System	08 Sep 2020 17:02:40

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 17:03:55

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 17:03:55

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	07 Sep 2020 17:12:42
User entered 'Day 27'	System	07 Sep 2020 17:12:42

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-09T13:22:11', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5afcca48-4eb4-4de6-9782-c55afab7b58e'	System	09 Sep 2020 17:22:17
User entered 'Some interference with activity (2)'	System	09 Sep 2020 17:22:17

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-09T13:22:14', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5afcca48-4eb4-4de6-9782-c55afab7b58e'	System	09 Sep 2020 17:22:17
User entered '09 Sep 2020 13:22'	System	09 Sep 2020 17:22:17

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 17:12:42

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 17:12:42

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	08 Sep 2020 17:02:40
User entered 'Day 28'	System	08 Sep 2020 17:02:40

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-10T19:02:32', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'bbb36477-24e1-4760-bc67-5ac46e480e69'	System	10 Sep 2020 23:02:40
User entered 'Some interference with activity (2)'	System	10 Sep 2020 23:02:40

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-10T19:02:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'bbb36477-24e1-4760-bc67-5ac46e480e69'	System	10 Sep 2020 23:02:40
User entered '10 Sep 2020 19:02'	System	10 Sep 2020 23:02:40

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:02:40

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(28)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:02:40

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	09 Sep 2020 17:22:17
User entered 'Day 29'	System	09 Sep 2020 17:22:17

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-11T12:31:04', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5f4c36b9-e090-42e6-b05c-5abcefd7a4f2'	System	11 Sep 2020 16:31:11
User entered 'Some interference with activity (2)'	System	11 Sep 2020 16:31:11

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-11T12:31:06', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5f4c36b9-e090-42e6-b05c-5abcefd7a4f2'	System	11 Sep 2020 16:31:11
User entered '11 Sep 2020 12:31'	System	11 Sep 2020 16:31:11

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:22:17

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(29)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:22:17

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	10 Sep 2020 23:02:40
User entered 'Day 30'	System	10 Sep 2020 23:02:40

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-12T12:40:03', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '86535858-a9cc-4b51-9708-54c4f585baa1'	System	12 Sep 2020 17:40:10
User entered 'Some interference with activity (2)'	System	12 Sep 2020 17:40:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-12T12:40:06', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '86535858-a9cc-4b51-9708-54c4f585baa1'	System	12 Sep 2020 17:40:10
User entered '12 Sep 2020 12:40'	System	12 Sep 2020 17:40:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 23:02:40

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(30)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 23:02:40

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(31)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	11 Sep 2020 16:31:11
User entered 'Day 31'	System	11 Sep 2020 16:31:11

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(31)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(31)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(31)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:31:11

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(31)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:31:11

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(32)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	12 Sep 2020 17:40:10
User entered 'Day 32'	System	12 Sep 2020 17:40:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(32)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(32)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(32)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:40:10

US3202191

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(32)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:40:10

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	19 Aug 2020 17:20:29
User entered 'Day 8'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-21T12:03:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9e2db9f2-8a75-4d04-9914-c092f74f0dc8'	System	21 Aug 2020 16:03:44
User entered 'Some interference with activity (2)'	System	21 Aug 2020 16:03:44

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-21T12:03:38', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9e2db9f2-8a75-4d04-9914-c092f74f0dc8'	System	21 Aug 2020 16:03:44
User entered '21 Aug 2020 12:03'	System	21 Aug 2020 16:03:44

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	20 Aug 2020 18:37:35
User entered 'Day 9'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-22T13:11:01', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'd1bb236f-4458-4e54-a54e-e442016e4886'	System	22 Aug 2020 17:11:07
User entered 'Some interference with activity (2)'	System	22 Aug 2020 17:11:07

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-22T13:11:05', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'd1bb236f-4458-4e54-a54e-e442016e4886'	System	22 Aug 2020 17:11:07
User entered '22 Aug 2020 13:11'	System	22 Aug 2020 17:11:07

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	21 Aug 2020 16:03:44
User entered 'Day 10'	System	21 Aug 2020 16:03:44

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-23T12:02:39', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'bace8734-9c99-4238-9d6a-2d47fd4a750b'	System	23 Aug 2020 16:02:43
User entered 'Some interference with activity (2)'	System	23 Aug 2020 16:02:43

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-23T12:02:42', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'bace8734-9c99-4238-9d6a-2d47fd4a750b'	System	23 Aug 2020 16:02:43
User entered '23 Aug 2020 12:02'	System	23 Aug 2020 16:02:43

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:03:44

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:03:44

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	22 Aug 2020 17:11:07
User entered 'Day 11'	System	22 Aug 2020 17:11:07

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-24T12:03:16', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cc016c44-60e3-4f12-8f74-1b355e75a8b2'	System	24 Aug 2020 16:03:23
User entered 'Some interference with activity (2)'	System	24 Aug 2020 16:03:23

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-24T12:03:20', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cc016c44-60e3-4f12-8f74-1b355e75a8b2'	System	24 Aug 2020 16:03:23
User entered '24 Aug 2020 12:03'	System	24 Aug 2020 16:03:23

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:11:07

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:11:07

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	23 Aug 2020 16:02:43
User entered 'Day 12'	System	23 Aug 2020 16:02:43

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 16:02:43

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 16:02:43

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Aug 2020 16:03:23
User entered 'Day 13'	System	24 Aug 2020 16:03:23

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-26T13:05:14', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3d69eb4c-3bdb-4f5b-8e84-93d7811bc366'	System	26 Aug 2020 17:05:18
User entered 'Some interference with activity (2)'	System	26 Aug 2020 17:05:18

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-26T13:05:16', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3d69eb4c-3bdb-4f5b-8e84-93d7811bc366'	System	26 Aug 2020 17:05:18
User entered '26 Aug 2020 13:05'	System	26 Aug 2020 17:05:18

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 16:03:23

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 16:03:23

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	26 Aug 2020 17:05:18
User entered 'Day 14'	System	26 Aug 2020 17:05:18

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-27T13:01:41', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a2e0e99e-de83-4ba5-ae31-1acd4a87f9c5'	System	27 Aug 2020 17:02:21
User entered 'Some interference with activity (2)'	System	27 Aug 2020 17:02:21

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-27T13:01:44', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a2e0e99e-de83-4ba5-ae31-1acd4a87f9c5'	System	27 Aug 2020 17:02:21
User entered '27 Aug 2020 13:01'	System	27 Aug 2020 17:02:21

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:05:18

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:05:18

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	26 Aug 2020 17:05:18
User entered 'Day 15'	System	26 Aug 2020 17:05:18

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-28T13:16:35', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c15893d5-b821-478e-93c0-3d59f099d84b'	System	28 Aug 2020 18:16:42
User entered 'Some interference with activity (2)'	System	28 Aug 2020 18:16:42

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-28T13:16:38', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c15893d5-b821-478e-93c0-3d59f099d84b'	System	28 Aug 2020 18:16:42
User entered '28 Aug 2020 13:16'	System	28 Aug 2020 18:16:42

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:05:18

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:05:18

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	27 Aug 2020 17:02:21
User entered 'Day 16'	System	27 Aug 2020 17:02:21

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-29T12:04:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3ac699a3-4cae-4745-85af-74601b567d04'	System	29 Aug 2020 17:04:53
User entered 'Some interference with activity (2)'	System	29 Aug 2020 17:04:53

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-29T12:04:48', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3ac699a3-4cae-4745-85af-74601b567d04'	System	29 Aug 2020 17:04:53
User entered '29 Aug 2020 12:04'	System	29 Aug 2020 17:04:53

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 17:02:21

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 17:02:21

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	28 Aug 2020 18:16:42
User entered 'Day 17'	System	28 Aug 2020 18:16:42

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-30T12:50:59', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9b9abe8b-584e-469f-b03f-6dd8b6ab2699'	System	30 Aug 2020 17:51:07
User entered 'Some interference with activity (2)'	System	30 Aug 2020 17:51:07

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-30T12:51:03', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9b9abe8b-584e-469f-b03f-6dd8b6ab2699'	System	30 Aug 2020 17:51:07
User entered '30 Aug 2020 12:51'	System	30 Aug 2020 17:51:07

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:16:42

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:16:42

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	29 Aug 2020 17:04:53
User entered 'Day 18'	System	29 Aug 2020 17:04:53

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-31T12:13:42', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '38529e50-9d38-4b39-bf9f-6948ab7a05f0'	System	31 Aug 2020 17:23:48
User entered 'Some interference with activity (2)'	System	31 Aug 2020 17:23:48

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-31T12:13:44', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '38529e50-9d38-4b39-bf9f-6948ab7a05f0'	System	31 Aug 2020 17:23:48
User entered '31 Aug 2020 12:13'	System	31 Aug 2020 17:23:48

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 17:04:53

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 17:04:53

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	30 Aug 2020 17:51:07
User entered 'Day 19'	System	30 Aug 2020 17:51:07

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-01T16:02:04', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '224dff17-8bc5-47a3-a769-cc10c2776975'	System	01 Sep 2020 20:02:10
User entered 'Some interference with activity (2)'	System	01 Sep 2020 20:02:10

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-01T16:02:07', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '224dff17-8bc5-47a3-a769-cc10c2776975'	System	01 Sep 2020 20:02:10
User entered '01 Sep 2020 16:02'	System	01 Sep 2020 20:02:10

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 17:51:07

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 17:51:07

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	31 Aug 2020 17:23:48
User entered 'Day 20'	System	31 Aug 2020 17:23:48

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-02T12:05:55', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '067a6b3b-dd5c-4d68-8925-a7bee9254469'	System	02 Sep 2020 17:06:01
User entered 'Some interference with activity (2)'	System	02 Sep 2020 17:06:01

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-02T12:05:58', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '067a6b3b-dd5c-4d68-8925-a7bee9254469'	System	02 Sep 2020 17:06:01
User entered '02 Sep 2020 12:05'	System	02 Sep 2020 17:06:01

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:23:48

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:23:48

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	01 Sep 2020 20:02:10
User entered 'Day 21'	System	01 Sep 2020 20:02:10

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-03T12:38:58', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ba533fa9-2676-480d-9a21-711402596ebe'	System	03 Sep 2020 17:39:04
User entered 'Some interference with activity (2)'	System	03 Sep 2020 17:39:04

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-03T12:39:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ba533fa9-2676-480d-9a21-711402596ebe'	System	03 Sep 2020 17:39:04
User entered '03 Sep 2020 12:39'	System	03 Sep 2020 17:39:04

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:02:10

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:02:10

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	02 Sep 2020 17:06:01
User entered 'Day 22'	System	02 Sep 2020 17:06:01

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-04T12:02:13', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '340ee18c-4abb-4c67-bc40-8fb2bcf92575'	System	04 Sep 2020 17:03:21
User entered 'Some interference with activity (2)'	System	04 Sep 2020 17:03:21

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-04T12:02:16', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '340ee18c-4abb-4c67-bc40-8fb2bcf92575'	System	04 Sep 2020 17:03:21
User entered '04 Sep 2020 12:02'	System	04 Sep 2020 17:03:21

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:06:01

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:06:01

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	03 Sep 2020 17:39:04
User entered 'Day 23'	System	03 Sep 2020 17:39:04

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-05T12:01:20', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e679b3e6-b78f-4dc3-83b3-2602bf4704cb'	System	05 Sep 2020 17:01:39
User entered 'Some interference with activity (2)'	System	05 Sep 2020 17:01:39

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-05T12:01:22', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e679b3e6-b78f-4dc3-83b3-2602bf4704cb' User entered '05 Sep 2020 12:01'	System	05 Sep 2020 17:01:39
	System	05 Sep 2020 17:01:39

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:39:04

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:39:04

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	04 Sep 2020 17:03:21
User entered 'Day 24'	System	04 Sep 2020 17:03:21

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-06T12:03:54', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e8e008eb-90f2-4b01-8f72-d0795d95327d'	System	06 Sep 2020 17:04:01
User entered 'Some interference with activity (2)'	System	06 Sep 2020 17:04:01

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-06T12:03:56', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e8e008eb-90f2-4b01-8f72-d0795d95327d'	System	06 Sep 2020 17:04:01
User entered '06 Sep 2020 12:03'	System	06 Sep 2020 17:04:01

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 17:03:21

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 17:03:21

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	05 Sep 2020 17:01:39
User entered 'Day 25'	System	05 Sep 2020 17:01:39

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-07T12:12:43', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '0f2449bb-100a-49ca-ae11-5666377ccca6'	System	07 Sep 2020 17:12:58
User entered 'Some interference with activity (2)'	System	07 Sep 2020 17:12:58

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-07T12:12:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '0f2449bb-100a-49ca-ae11-5666377ccca6'	System	07 Sep 2020 17:12:58
User entered '07 Sep 2020 12:12'	System	07 Sep 2020 17:12:58

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:01:39

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:01:39

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	06 Sep 2020 17:04:01
User entered 'Day 26'	System	06 Sep 2020 17:04:01

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-08T13:01:32', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '15eb5b0a-f14c-402f-9b4c-6da52b55cc45'	System	08 Sep 2020 17:02:48
User entered 'Some interference with activity (2)'	System	08 Sep 2020 17:02:48

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-08T13:01:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '15eb5b0a-f14c-402f-9b4c-6da52b55cc45'	System	08 Sep 2020 17:02:48
User entered '08 Sep 2020 13:01'	System	08 Sep 2020 17:02:48

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 17:04:01

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 17:04:01

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	07 Sep 2020 17:12:58
User entered 'Day 27'	System	07 Sep 2020 17:12:58

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-09T13:22:18', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b841abb9-9201-46a7-9671-cd357c95584f'	System	09 Sep 2020 17:22:25
User entered 'Some interference with activity (2)'	System	09 Sep 2020 17:22:25

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-09T13:22:20', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b841abb9-9201-46a7-9671-cd357c95584f' User entered '09 Sep 2020 13:22'	System	09 Sep 2020 17:22:25
	System	09 Sep 2020 17:22:25

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 17:12:58

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 17:12:58

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	08 Sep 2020 17:02:48
User entered 'Day 28'	System	08 Sep 2020 17:02:48

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-10T19:02:40', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3311687d-214b-46ef-a086-ee06a235186c'	System	10 Sep 2020 23:02:47
User entered 'Some interference with activity (2)'	System	10 Sep 2020 23:02:47

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-10T19:02:42', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3311687d-214b-46ef-a086-ee06a235186c'	System	10 Sep 2020 23:02:47
User entered '10 Sep 2020 19:02'	System	10 Sep 2020 23:02:47

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:02:48

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(28)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:02:48

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	09 Sep 2020 17:22:25
User entered 'Day 29'	System	09 Sep 2020 17:22:25

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-11T12:31:12', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'af6cb63a-8b80-4067-a930-e491f32cfcac'	System	11 Sep 2020 16:31:19
User entered 'Some interference with activity (2)'	System	11 Sep 2020 16:31:19

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-11T12:31:13', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'af6cb63a-8b80-4067-a930-e491f32cfcac'	System	11 Sep 2020 16:31:19
User entered '11 Sep 2020 12:31'	System	11 Sep 2020 16:31:19

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:22:25

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(29)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:22:25

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	10 Sep 2020 23:02:47
User entered 'Day 30'	System	10 Sep 2020 23:02:47

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-12T12:40:10', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'bc400ce8-fa5a-4b76-b42c-0e2747747f5c'	System	12 Sep 2020 17:40:17
User entered 'Some interference with activity (2)'	System	12 Sep 2020 17:40:17

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-12T12:40:12', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'bc400ce8-fa5a-4b76-b42c-0e2747747f5c'	System	12 Sep 2020 17:40:17
User entered '12 Sep 2020 12:40'	System	12 Sep 2020 17:40:17

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 23:02:47

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(30)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 23:02:47

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(31)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	11 Sep 2020 16:31:19
User entered 'Day 31'	System	11 Sep 2020 16:31:19

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(31)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(31)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(31)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:31:19

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(31)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:31:19

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(32)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	12 Sep 2020 17:40:17
User entered 'Day 32'	System	12 Sep 2020 17:40:17

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(32)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(32)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(32)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:40:17

US3202191

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(32)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:40:17

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	19 Aug 2020 17:20:29
User entered 'Day 8'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-21T12:03:45', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '8a86c83c-444c-4c02-9a0b-4bf31bdcd206'	System	21 Aug 2020 16:03:52
User entered 'Some interference with activity (2)'	System	21 Aug 2020 16:03:52

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-21T12:03:49', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '8a86c83c-444c-4c02-9a0b-4bf31bdcd206'	System	21 Aug 2020 16:03:52
User entered '21 Aug 2020 12:03'	System	21 Aug 2020 16:03:52

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:20:29

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	20 Aug 2020 18:37:35
User entered 'Day 9'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-22T13:11:11', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '633da157-16ae-41db-9043-5cd2f14fe4b0'	System	22 Aug 2020 17:11:17
User entered 'Some interference with activity (2)'	System	22 Aug 2020 17:11:17

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-22T13:11:15', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '633da157-16ae-41db-9043-5cd2f14fe4b0'	System	22 Aug 2020 17:11:17
User entered '22 Aug 2020 13:11'	System	22 Aug 2020 17:11:17

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 18:37:35

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	21 Aug 2020 16:03:52
User entered 'Day 10'	System	21 Aug 2020 16:03:52

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-23T12:02:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fc9d9af7-3ebb-40e6-af81-ae7fd0f58851'	System	23 Aug 2020 16:02:51
User entered 'Some interference with activity (2)'	System	23 Aug 2020 16:02:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-23T12:02:49', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'fc9d9af7-3ebb-40e6-af81-ae7fd0f58851'	System	23 Aug 2020 16:02:51
User entered '23 Aug 2020 12:02'	System	23 Aug 2020 16:02:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:03:52

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:03:52

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	22 Aug 2020 17:11:17
User entered 'Day 11'	System	22 Aug 2020 17:11:17

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-24T12:03:25', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '31a3cc1d-af6e-443d-b154-5f5f99133579'	System	24 Aug 2020 16:03:34
User entered 'Some interference with activity (2)'	System	24 Aug 2020 16:03:34

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-24T12:03:29', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '31a3cc1d-af6e-443d-b154-5f5f99133579'	System	24 Aug 2020 16:03:34
User entered '24 Aug 2020 12:03'	System	24 Aug 2020 16:03:34

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:11:17

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:11:17

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	23 Aug 2020 16:02:51
User entered 'Day 12'	System	23 Aug 2020 16:02:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 16:02:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 16:02:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Aug 2020 16:03:34
User entered 'Day 13'	System	24 Aug 2020 16:03:34

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-26T13:05:21', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9966f296-c57e-40f1-8f33-28653e048077'	System	26 Aug 2020 17:05:28
User entered 'Some interference with activity (2)'	System	26 Aug 2020 17:05:28

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-26T13:05:25', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9966f296-c57e-40f1-8f33-28653e048077'	System	26 Aug 2020 17:05:28
User entered '26 Aug 2020 13:05'	System	26 Aug 2020 17:05:28

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 16:03:34

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 16:03:34

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	26 Aug 2020 17:05:28
User entered 'Day 14'	System	26 Aug 2020 17:05:28

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-27T13:01:53', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '32398859-4a7e-4841-972e-355452b4a202'	System	27 Aug 2020 17:02:37
User entered 'Some interference with activity (2)'	System	27 Aug 2020 17:02:37

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-27T13:01:56', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '32398859-4a7e-4841-972e-355452b4a202'	System	27 Aug 2020 17:02:37
User entered '27 Aug 2020 13:01'	System	27 Aug 2020 17:02:37

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:05:28

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:05:28

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	26 Aug 2020 17:05:28
User entered 'Day 15'	System	26 Aug 2020 17:05:28

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-28T13:16:43', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b5dc53a1-4b79-48d1-aa5f-832cafd5f2b7'	System	28 Aug 2020 18:16:51
User entered 'Some interference with activity (2)'	System	28 Aug 2020 18:16:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-28T13:16:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b5dc53a1-4b79-48d1-aa5f-832cafd5f2b7'	System	28 Aug 2020 18:16:51
User entered '28 Aug 2020 13:16'	System	28 Aug 2020 18:16:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:05:28

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:05:28

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	27 Aug 2020 17:02:37
User entered 'Day 16'	System	27 Aug 2020 17:02:37

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-29T12:04:53', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6d788d21-7c11-4384-ab3c-831c0db8dd6b'	System	29 Aug 2020 17:04:58
User entered 'Some interference with activity (2)'	System	29 Aug 2020 17:04:58

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-29T12:04:56', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6d788d21-7c11-4384-ab3c-831c0db8dd6b'	System	29 Aug 2020 17:04:58
User entered '29 Aug 2020 12:04'	System	29 Aug 2020 17:04:58

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 17:02:37

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 17:02:37

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	28 Aug 2020 18:16:51
User entered 'Day 17'	System	28 Aug 2020 18:16:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-30T12:51:07', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '387457cd-cbf5-4120-a738-3d26f4d5a0e7'	System	30 Aug 2020 17:51:14
User entered 'Some interference with activity (2)'	System	30 Aug 2020 17:51:14

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-30T12:51:09', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '387457cd-cbf5-4120-a738-3d26f4d5a0e7'	System	30 Aug 2020 17:51:14
User entered '30 Aug 2020 12:51'	System	30 Aug 2020 17:51:14

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:16:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:16:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	29 Aug 2020 17:04:58
User entered 'Day 18'	System	29 Aug 2020 17:04:58

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-31T12:13:50', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '4df7abec-c73e-45f9-8788-457647de3b17'	System	31 Aug 2020 17:23:52
User entered 'Some interference with activity (2)'	System	31 Aug 2020 17:23:52

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-31T12:13:53', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '4df7abec-c73e-45f9-8788-457647de3b17'	System	31 Aug 2020 17:23:52
User entered '31 Aug 2020 12:13'	System	31 Aug 2020 17:23:52

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 17:04:58

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 17:04:58

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	30 Aug 2020 17:51:14
User entered 'Day 19'	System	30 Aug 2020 17:51:14

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-01T16:02:11', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cce630fd-2b1f-4c0f-9d78-547eeaf06fe7'	System	01 Sep 2020 20:02:17
User entered 'Some interference with activity (2)'	System	01 Sep 2020 20:02:17

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-01T16:02:14', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cce630fd-2b1f-4c0f-9d78-547eeaf06fe7'	System	01 Sep 2020 20:02:17
User entered '01 Sep 2020 16:02'	System	01 Sep 2020 20:02:17

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 17:51:14

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 17:51:14

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	31 Aug 2020 17:23:52
User entered 'Day 20'	System	31 Aug 2020 17:23:52

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-02T12:06:02', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e64b35e4-23d6-4616-8491-63f1ab914552'	System	02 Sep 2020 17:06:11
User entered 'Some interference with activity (2)'	System	02 Sep 2020 17:06:11

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-02T12:06:05', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e64b35e4-23d6-4616-8491-63f1ab914552'	System	02 Sep 2020 17:06:11
User entered '02 Sep 2020 12:06'	System	02 Sep 2020 17:06:11

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:23:52

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:23:52

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	01 Sep 2020 20:02:17
User entered 'Day 21'	System	01 Sep 2020 20:02:17

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-03T12:39:04', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '20c7e205-ddac-4d35-a1e7-63d3c3481c1f'	System	03 Sep 2020 17:39:09
User entered 'Some interference with activity (2)'	System	03 Sep 2020 17:39:09

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-03T12:39:07', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '20c7e205-ddac-4d35-a1e7-63d3c3481c1f'	System	03 Sep 2020 17:39:09
User entered '03 Sep 2020 12:39'	System	03 Sep 2020 17:39:09

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:02:17

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:02:17

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	02 Sep 2020 17:06:11
User entered 'Day 22'	System	02 Sep 2020 17:06:11

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-04T12:02:20', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b83996c5-6bc7-42d0-bb07-7c85120a1e6b'	System	04 Sep 2020 17:03:27
User entered 'Some interference with activity (2)'	System	04 Sep 2020 17:03:27

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-04T12:02:23', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b83996c5-6bc7-42d0-bb07-7c85120a1e6b'	System	04 Sep 2020 17:03:27
User entered '04 Sep 2020 12:02'	System	04 Sep 2020 17:03:27

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:06:11

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:06:11

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	03 Sep 2020 17:39:09
User entered 'Day 23'	System	03 Sep 2020 17:39:09

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-05T12:01:27', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'abe1ba3f-2e75-4912-bdb7-d6c93bbf9487'	System	05 Sep 2020 17:01:42
User entered 'Some interference with activity (2)'	System	05 Sep 2020 17:01:42

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-05T12:01:29', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'abe1ba3f-2e75-4912-bdb7-d6c93bbf9487'	System	05 Sep 2020 17:01:42
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 17:01:42

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:39:09

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:39:09

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	04 Sep 2020 17:03:27
User entered 'Day 24'	System	04 Sep 2020 17:03:27

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-06T12:04:01', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'f0bef6d9-f6b7-4789-a2d2-1c75148e0dad'	System	06 Sep 2020 17:04:07
User entered 'Some interference with activity (2)'	System	06 Sep 2020 17:04:07

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-06T12:04:03', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'f0bef6d9-f6b7-4789-a2d2-1c75148e0dad'	System	06 Sep 2020 17:04:07
User entered '06 Sep 2020 12:04'	System	06 Sep 2020 17:04:07

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 17:03:27

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 17:03:27

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	05 Sep 2020 17:01:42
User entered 'Day 25'	System	05 Sep 2020 17:01:42

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-07T12:12:50', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b32e1165-b9d2-4138-a51e-1e05998534d1'	System	07 Sep 2020 17:13:06
User entered 'Some interference with activity (2)'	System	07 Sep 2020 17:13:06

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-07T12:12:54', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b32e1165-b9d2-4138-a51e-1e05998534d1'	System	07 Sep 2020 17:13:06
User entered '07 Sep 2020 12:12'	System	07 Sep 2020 17:13:06

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:01:42

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:01:42

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	06 Sep 2020 17:04:07
User entered 'Day 26'	System	06 Sep 2020 17:04:07

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-08T13:01:38', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '72d9a393-c028-496d-a483-a20469a285c4'	System	08 Sep 2020 17:02:56
User entered 'Some interference with activity (2)'	System	08 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-08T13:01:41', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '72d9a393-c028-496d-a483-a20469a285c4'	System	08 Sep 2020 17:02:56
User entered '08 Sep 2020 13:01'	System	08 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 17:04:07

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 17:04:07

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	07 Sep 2020 17:13:06
User entered 'Day 27'	System	07 Sep 2020 17:13:06

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-09T13:22:24', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e91f95d1-b204-4b2b-b8f1-fa3899efb9b1'	System	09 Sep 2020 17:22:33
User entered 'Some interference with activity (2)'	System	09 Sep 2020 17:22:33

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-09T13:22:27', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e91f95d1-b204-4b2b-b8f1-fa3899efb9b1'	System	09 Sep 2020 17:22:33
User entered '09 Sep 2020 13:22'	System	09 Sep 2020 17:22:33

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 17:13:06

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 17:13:06

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	08 Sep 2020 17:02:56
User entered 'Day 28'	System	08 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-10T19:02:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5ee5da3c-707d-4bd7-a8a4-0b2810ca8e92'	System	10 Sep 2020 23:02:51
User entered 'Some interference with activity (2)'	System	10 Sep 2020 23:02:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-10T19:02:49', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5ee5da3c-707d-4bd7-a8a4-0b2810ca8e92'	System	10 Sep 2020 23:02:51
User entered '10 Sep 2020 19:02'	System	10 Sep 2020 23:02:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(28)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	09 Sep 2020 17:22:33
User entered 'Day 29'	System	09 Sep 2020 17:22:33

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-11T12:31:20', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '66e41186-62fe-4276-bff9-2187be93200e'	System	11 Sep 2020 16:31:26
User entered 'Some interference with activity (2)'	System	11 Sep 2020 16:31:26

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-11T12:31:21', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '66e41186-62fe-4276-bff9-2187be93200e'	System	11 Sep 2020 16:31:26
User entered '11 Sep 2020 12:31'	System	11 Sep 2020 16:31:26

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:22:33

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(29)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:22:33

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	10 Sep 2020 23:02:51
User entered 'Day 30'	System	10 Sep 2020 23:02:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-12T12:40:16', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'f4a15434-8c0a-4522-9352-b0cab2813d6b'	System	12 Sep 2020 17:40:23
User entered 'Some interference with activity (2)'	System	12 Sep 2020 17:40:23

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-12T12:40:19', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'f4a15434-8c0a-4522-9352-b0cab2813d6b'	System	12 Sep 2020 17:40:23
User entered '12 Sep 2020 12:40'	System	12 Sep 2020 17:40:23

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 23:02:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(30)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 23:02:51

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	11 Sep 2020 16:31:26
User entered 'Day 31'	System	11 Sep 2020 16:31:26

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:31:26

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(31)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:31:26

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	12 Sep 2020 17:40:23
User entered 'Day 32'	System	12 Sep 2020 17:40:23

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 15:41:09

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:40:23

US3202191

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(32)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:40:23

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	19 Aug 2020 17:19:17
User entered 'Day 8'	System	19 Aug 2020 17:19:17

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-21T12:03:57', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'f5ad9584-9cdd-44aa-8d0c-8f91ef52059a'	System	21 Aug 2020 16:04:04
User entered 'No (N)'	System	21 Aug 2020 16:04:04

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-21T12:04:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'f5ad9584-9cdd-44aa-8d0c-8f91ef52059a'	System	21 Aug 2020 16:04:04
User entered '21 Aug 2020 12:04'	System	21 Aug 2020 16:04:04

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:19:17

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:19:17

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	20 Aug 2020 18:36:17
User entered 'Day 9'	System	20 Aug 2020 18:36:17

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-22T13:11:21', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '64de1ca5-dfad-4eb8-9d47-e0198fbc6fb2'	System	22 Aug 2020 17:11:29
User entered 'No (N)'	System	22 Aug 2020 17:11:29

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-22T13:11:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '64de1ca5-dfad-4eb8-9d47-e0198fbc6fb2'	System	22 Aug 2020 17:11:29
User entered '22 Aug 2020 13:11'	System	22 Aug 2020 17:11:29

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 18:36:17

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 18:36:17

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	21 Aug 2020 16:03:01
User entered 'Day 10'	System	21 Aug 2020 16:03:01

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-23T12:02:57', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a70594e0-e42f-4020-b115-5de74c280857'	System	23 Aug 2020 16:03:02
User entered 'No (N)'	System	23 Aug 2020 16:03:02

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-23T12:03:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a70594e0-e42f-4020-b115-5de74c280857'	System	23 Aug 2020 16:03:02
User entered '23 Aug 2020 12:03'	System	23 Aug 2020 16:03:02

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:03:01

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:03:01

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	22 Aug 2020 17:10:47
User entered 'Day 11'	System	22 Aug 2020 17:10:47

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-24T12:03:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b3a239c8-b30b-4dbd-a0f7-1664eb9863fd'	System	24 Aug 2020 16:03:41
User entered 'No (N)'	System	24 Aug 2020 16:03:41

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-24T12:03:39', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b3a239c8-b30b-4dbd-a0f7-1664eb9863fd'	System	24 Aug 2020 16:03:41
User entered '24 Aug 2020 12:03'	System	24 Aug 2020 16:03:41

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 17:10:47

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 17:10:47

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	23 Aug 2020 16:02:26
User entered 'Day 12'	System	23 Aug 2020 16:02:26

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 16:02:26

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 16:02:26

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Aug 2020 16:02:59
User entered 'Day 13'	System	24 Aug 2020 16:02:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-26T13:05:32', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1c7f8e76-1191-4058-bf3e-7f82f84461b4'	System	26 Aug 2020 17:05:38
User entered 'No (N)'	System	26 Aug 2020 17:05:38

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-26T13:05:35', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1c7f8e76-1191-4058-bf3e-7f82f84461b4'	System	26 Aug 2020 17:05:38
User entered '26 Aug 2020 13:05'	System	26 Aug 2020 17:05:38

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 16:02:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 16:02:59

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	26 Aug 2020 17:05:00
User entered 'Day 14'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-27T13:02:01', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '164efd51-5cb2-4a05-b0dc-e66c03b71392'	System	27 Aug 2020 17:02:43
User entered 'No (N)'	System	27 Aug 2020 17:02:43

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-27T13:02:05', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '164efd51-5cb2-4a05-b0dc-e66c03b71392'	System	27 Aug 2020 17:02:43
User entered '27 Aug 2020 13:02'	System	27 Aug 2020 17:02:43

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	26 Aug 2020 17:05:00
User entered 'Day 15'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-28T13:16:52', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c9eb7ef3-601e-4e61-af4b-1f27b7e2d8e8'	System	28 Aug 2020 18:17:01
User entered 'No (N)'	System	28 Aug 2020 18:17:01

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-28T13:16:55', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c9eb7ef3-601e-4e61-af4b-1f27b7e2d8e8'	System	28 Aug 2020 18:17:01
User entered '28 Aug 2020 13:16'	System	28 Aug 2020 18:17:01

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:05:00

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	27 Aug 2020 17:01:51
User entered 'Day 16'	System	27 Aug 2020 17:01:51

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-29T12:05:01', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '77936860-899e-4e01-af49-1b1aad207af4'	System	29 Aug 2020 17:05:08
User entered 'No (N)'	System	29 Aug 2020 17:05:08

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-29T12:05:03', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '77936860-899e-4e01-af49-1b1aad207af4'	System	29 Aug 2020 17:05:08
User entered '29 Aug 2020 12:05'	System	29 Aug 2020 17:05:08

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 17:01:51

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 17:01:51

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	28 Aug 2020 18:16:27
User entered 'Day 17'	System	28 Aug 2020 18:16:27

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-30T12:51:14', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ff5b77e4-8d6b-4932-b3fb-1ff21ab2ff55'	System	30 Aug 2020 17:51:20
User entered 'No (N)'	System	30 Aug 2020 17:51:20

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-30T12:51:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ff5b77e4-8d6b-4932-b3fb-1ff21ab2ff55'	System	30 Aug 2020 17:51:20
User entered '30 Aug 2020 12:51'	System	30 Aug 2020 17:51:20

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 18:16:27

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 18:16:27

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	29 Aug 2020 17:04:39
User entered 'Day 18'	System	29 Aug 2020 17:04:39

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-31T12:14:01', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a2b68a93-e3ab-44c8-a238-320693724e84'	System	31 Aug 2020 17:23:55
User entered 'No (N)'	System	31 Aug 2020 17:23:55

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-08-31T12:14:04', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a2b68a93-e3ab-44c8-a238-320693724e84'	System	31 Aug 2020 17:23:55
User entered '31 Aug 2020 12:14'	System	31 Aug 2020 17:23:55

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 17:04:39

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 17:04:39

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	30 Aug 2020 17:50:46
User entered 'Day 19'	System	30 Aug 2020 17:50:46

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-01T16:02:19', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '558ea790-a408-4452-867b-b344d436e091'	System	01 Sep 2020 20:02:24
User entered 'No (N)'	System	01 Sep 2020 20:02:24

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-01T16:02:21', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '558ea790-a408-4452-867b-b344d436e091'	System	01 Sep 2020 20:02:24
User entered '01 Sep 2020 16:02'	System	01 Sep 2020 20:02:24

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 17:50:46

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 17:50:46

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	31 Aug 2020 17:20:55
User entered 'Day 20'	System	31 Aug 2020 17:20:55

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-02T12:06:10', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '68499f90-3115-4018-bf30-c635877794d1'	System	02 Sep 2020 17:06:16
User entered 'No (N)'	System	02 Sep 2020 17:06:16

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-02T12:06:12', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '68499f90-3115-4018-bf30-c635877794d1'	System	02 Sep 2020 17:06:16
User entered '02 Sep 2020 12:06'	System	02 Sep 2020 17:06:16

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:20:55

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:20:55

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	01 Sep 2020 20:01:58
User entered 'Day 21'	System	01 Sep 2020 20:01:58

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-03T12:39:12', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '659634a6-1ddb-4d3e-8b61-92fd761f2930'	System	03 Sep 2020 17:39:21
User entered 'No (N)'	System	03 Sep 2020 17:39:21

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-03T12:39:18', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '659634a6-1ddb-4d3e-8b61-92fd761f2930'	System	03 Sep 2020 17:39:21
User entered '03 Sep 2020 12:39'	System	03 Sep 2020 17:39:21

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 20:01:58

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 20:01:58

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	02 Sep 2020 17:05:46
User entered 'Day 22'	System	02 Sep 2020 17:05:46

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-04T12:02:29', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cb7f66a1-676e-4657-aa63-4fd4fbbb2825'	System	04 Sep 2020 17:03:38
User entered 'No (N)'	System	04 Sep 2020 17:03:38

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-04T12:02:32', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cb7f66a1-676e-4657-aa63-4fd4fbbb2825'	System	04 Sep 2020 17:03:38
User entered '04 Sep 2020 12:02'	System	04 Sep 2020 17:03:38

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 17:05:46

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 17:05:46

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	03 Sep 2020 17:38:46
User entered 'Day 23'	System	03 Sep 2020 17:38:46

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-05T12:01:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a6ab85a7-5351-4de9-b020-6d049c1496f6'	System	05 Sep 2020 17:01:54
User entered 'No (N)'	System	05 Sep 2020 17:01:54

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-05T12:01:41', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a6ab85a7-5351-4de9-b020-6d049c1496f6'	System	05 Sep 2020 17:01:54
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 17:01:54

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:38:46

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:38:46

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	04 Sep 2020 17:02:56
User entered 'Day 24'	System	04 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-06T12:04:09', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ceeb5d17-f442-4983-a7a8-7883c9cf0df9'	System	06 Sep 2020 17:04:15
User entered 'No (N)'	System	06 Sep 2020 17:04:15

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-06T12:04:12', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ceeb5d17-f442-4983-a7a8-7883c9cf0df9'	System	06 Sep 2020 17:04:15
User entered '06 Sep 2020 12:04'	System	06 Sep 2020 17:04:15

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 17:02:56

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	05 Sep 2020 17:01:21
User entered 'Day 25'	System	05 Sep 2020 17:01:21

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-07T12:12:59', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7df7bcbd-349f-40af-8057-6bdf45725f0b'	System	07 Sep 2020 17:13:07
User entered 'No (N)'	System	07 Sep 2020 17:13:07

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-07T12:13:02', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7df7bcbd-349f-40af-8057-6bdf45725f0b'	System	07 Sep 2020 17:13:07
User entered '07 Sep 2020 12:13'	System	07 Sep 2020 17:13:07

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:01:21

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(25)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:01:21

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	06 Sep 2020 17:03:50
User entered 'Day 26'	System	06 Sep 2020 17:03:50

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-08T13:01:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3fba0929-0ee1-4956-8ec1-79031b5dbe98'	System	08 Sep 2020 17:03:14
User entered 'No (N)'	System	08 Sep 2020 17:03:14

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-08T13:01:49', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '3fba0929-0ee1-4956-8ec1-79031b5dbe98'	System	08 Sep 2020 17:03:14
User entered '08 Sep 2020 13:01'	System	08 Sep 2020 17:03:14

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 17:03:50

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(26)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 17:03:50

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	07 Sep 2020 17:12:38
User entered 'Day 27'	System	07 Sep 2020 17:12:38

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-09T13:22:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '20c356de-59f2-4682-99d6-5492300675e2'	System	09 Sep 2020 17:22:44
User entered 'No (N)'	System	09 Sep 2020 17:22:44

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-09T13:22:40', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '20c356de-59f2-4682-99d6-5492300675e2'	System	09 Sep 2020 17:22:44
User entered '09 Sep 2020 13:22'	System	09 Sep 2020 17:22:44

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 17:12:38

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(27)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 17:12:38

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	08 Sep 2020 17:02:24
User entered 'Day 28'	System	08 Sep 2020 17:02:24

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-10T19:02:56', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1a70033a-8991-4fc7-8911-16f41b1bbb50'	System	10 Sep 2020 23:03:01
User entered 'No (N)'	System	10 Sep 2020 23:03:01

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-10T19:02:58', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1a70033a-8991-4fc7-8911-16f41b1bbb50'	System	10 Sep 2020 23:03:01
User entered '10 Sep 2020 19:02'	System	10 Sep 2020 23:03:01

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:02:24

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(28)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:02:24

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	09 Sep 2020 17:22:17
User entered 'Day 29'	System	09 Sep 2020 17:22:17

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-11T12:31:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '116b08ad-a2ea-49c7-98c8-bd4d574410f3'	System	11 Sep 2020 16:31:31
User entered 'No (N)'	System	11 Sep 2020 16:31:31

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-11T12:31:28', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '116b08ad-a2ea-49c7-98c8-bd4d574410f3'	System	11 Sep 2020 16:31:31
User entered '11 Sep 2020 12:31'	System	11 Sep 2020 16:31:31

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:22:17

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(29)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:22:17

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	10 Sep 2020 23:02:40
User entered 'Day 30'	System	10 Sep 2020 23:02:40

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-12T12:40:22', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ba70f801-a9b2-4afe-9e22-adbc55094850'	System	12 Sep 2020 17:40:28
User entered 'No (N)'	System	12 Sep 2020 17:40:28

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-12T12:40:25', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ba70f801-a9b2-4afe-9e22-adbc55094850'	System	12 Sep 2020 17:40:28
User entered '12 Sep 2020 12:40'	System	12 Sep 2020 17:40:28

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 23:02:40

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(30)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 23:02:40

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	11 Sep 2020 16:31:11
User entered 'Day 31'	System	11 Sep 2020 16:31:11

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 16:31:11

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(31)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 16:31:11

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	12 Sep 2020 17:40:10
User entered 'Day 32'	System	12 Sep 2020 17:40:10

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 17:40:10

US3202191

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(32)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 17:40:10

US3202191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	24 Aug 2020 17:09:42

US3202191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '24 Aug 2020'	(b) (4) Lilian Nukuna (b) (4) (b) (4)	24 Aug 2020 17:09:42

US3202191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	24 Aug 2020 17:09:42

US3202191

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	Lilian Nukuna (b) (4)	24 Aug 2020 17:09:42

US3202191

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	24 Aug 2020 17:09:48

US3202191

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'I'	System	24 Aug 2020 17:09:48

US3202191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:44:16

US3202191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '28 Aug 2020'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:44:16

US3202191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:44:16

US3202191

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4)	17 Sep 2020 22:44:16
	Erica Osmundsen (b) (4)	

US3202191

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:44:22

US3202191

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'I'	System	17 Sep 2020 22:44:22

US3202191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:44:58

US3202191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '4 Sep 2020'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:44:58

US3202191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:44:58

US3202191

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:44:58

US3202191

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:45:04

US3202191

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'I'	System	17 Sep 2020 22:45:04

US3202191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 14:18:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:58:50
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'The date is correct' (Site from System).	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:18:50
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	24 Sep 2020 14:18:42
User entered '24 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:18:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 14:18:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'VISIT2'	System	24 Sep 2020 14:18:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '24 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '09:10'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered '24 Sep 2020 09:10'	System	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '97.4' F	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '58'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'bpm'	System	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '18'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'breaths/min'	System	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '141'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'mmHg'	System	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '80'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:41:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'mmHg'	System	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '24 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '10:45'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered '24 Sep 2020 10:45'	System	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '39.9' C	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '58'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'bpm'	System	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '18'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'breaths/min'	System	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '136'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'mmHg'	System	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '86'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:41:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'mmHg'	System	24 Sep 2020 22:02:42

US3202191

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 14:18:58

US3202191

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 14:18:58

US3202191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 14:18:25

US3202191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 14:18:25

US3202191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 14:18:25

US3202191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 14:18:25

US3202191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User closed query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 10:19:32
Query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''.' answered with 'OOV-Scheduling conflict between site and subject' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 13:47:17
User opened query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 17:15:28
User entered '24 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:18:25

US3202191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '10:06'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 14:18:25

US3202191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered '24 Sep 2020 10:06'	System	24 Sep 2020 14:18:25

US3202191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 14:18:25

US3202191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'ONCE'	System	24 Sep 2020 14:18:25

US3202191

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:41:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 14:18:25

US3202191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 15:22:31

US3202191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '24 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 15:22:31

US3202191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '09:26'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 15:22:31

US3202191

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered '24 Sep 2020 09:26'	System	24 Sep 2020 15:22:31

US3202191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:41:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '24 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 15:22:43

US3202191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4)	24 Sep 2020 15:22:43

US3202191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 15:22:43

US3202191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:09

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '09:24'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 15:22:43

US3202191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:41:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered '24 Sep 2020 09:24'	System	24 Sep 2020 15:22:43

US3202191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4)	24 Sep 2020 15:22:43

US3202191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 15:22:43

US3202191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 15:22:43

US3202191

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:41:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered empty.	System	24 Sep 2020 15:22:43

US3202191

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	24 Sep 2020 14:18:33

US3202191

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'I'	System	24 Sep 2020 14:18:33

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:46:09', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '04758b84-cd34-4c70-a835-677fa26b0866'	System	24 Sep 2020 14:46:56
User entered 'Yes (Y)'	System	24 Sep 2020 14:46:56

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:46:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '04758b84-cd34-4c70-a835-677fa26b0866'	System	24 Sep 2020 14:46:56
User entered '98.5'	System	24 Sep 2020 14:46:56

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:46:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '04758b84-cd34-4c70-a835-677fa26b0866'	System	24 Sep 2020 14:46:56
User entered 'No (N)'	System	24 Sep 2020 14:46:56

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:46:41', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '04758b84-cd34-4c70-a835-677fa26b0866'	System	24 Sep 2020 14:46:56
User entered '24 Sep 2020 10:46'	System	24 Sep 2020 14:46:56

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Sep 2020 10:26'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Sep 2020 12:56'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:23:24', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a6b5deb2-a9fd-4c78-993e-0255602bc502'	System	24 Sep 2020 19:23:48
User entered 'Yes (Y)'	System	24 Sep 2020 19:23:48

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:23:32', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a6b5deb2-a9fd-4c78-993e-0255602bc502'	System	24 Sep 2020 19:23:48
User entered '97.3'	System	24 Sep 2020 19:23:48

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:23:38', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a6b5deb2-a9fd-4c78-993e-0255602bc502'	System	24 Sep 2020 19:23:48
User entered 'No (N)'	System	24 Sep 2020 19:23:48

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:23:42', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a6b5deb2-a9fd-4c78-993e-0255602bc502'	System	24 Sep 2020 19:23:48
User entered '24 Sep 2020 15:23'	System	24 Sep 2020 19:23:48

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Sep 2020 13:51'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 2'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:39:06', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1bab4c9b-9341-43d1-aa93-582cbe44e826'	System	25 Sep 2020 17:39:29
User entered 'Yes (Y)'	System	25 Sep 2020 17:39:29

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:39:13', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1bab4c9b-9341-43d1-aa93-582cbe44e826' User entered '97.3'	System	25 Sep 2020 17:39:29
	System	25 Sep 2020 17:39:29

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:39:19', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1bab4c9b-9341-43d1-aa93-582cbe44e826'	System	25 Sep 2020 17:39:29
User entered 'No (N)'	System	25 Sep 2020 17:39:29

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:39:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1bab4c9b-9341-43d1-aa93-582cbe44e826'	System	25 Sep 2020 17:39:29
User entered '25 Sep 2020 13:39'	System	25 Sep 2020 17:39:29

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 3'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:01:10', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9819b9ba-4fbb-46c5-98a8-17e4c380ff74'	System	26 Sep 2020 16:02:16
User entered 'Yes (Y)'	System	26 Sep 2020 16:02:16

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:01:16', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9819b9ba-4fbb-46c5-98a8-17e4c380ff74'	System	26 Sep 2020 16:02:16
User entered '97.5'	System	26 Sep 2020 16:02:16

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:01:21', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9819b9ba-4fbb-46c5-98a8-17e4c380ff74'	System	26 Sep 2020 16:02:16
User entered 'No (N)'	System	26 Sep 2020 16:02:16

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:01:25', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9819b9ba-4fbb-46c5-98a8-17e4c380ff74'	System	26 Sep 2020 16:02:16
User entered '26 Sep 2020 12:01'	System	26 Sep 2020 16:02:16

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 4'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:08:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c6acbf0b-4be5-421a-ad0d-df85f9e14acc'	System	27 Sep 2020 16:08:39
User entered 'Yes (Y)'	System	27 Sep 2020 16:08:39

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:08:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c6acbf0b-4be5-421a-ad0d-df85f9e14acc'	System	27 Sep 2020 16:08:39
User entered '97.5'	System	27 Sep 2020 16:08:39

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:08:32', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c6acbf0b-4be5-421a-ad0d-df85f9e14acc'	System	27 Sep 2020 16:08:39
User entered 'No (N)'	System	27 Sep 2020 16:08:39

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:08:35', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c6acbf0b-4be5-421a-ad0d-df85f9e14acc'	System	27 Sep 2020 16:08:39
User entered '27 Sep 2020 12:08'	System	27 Sep 2020 16:08:39

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 5'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:26:19', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '4a796469-09c1-47e8-934f-415ed1ef31a7'	System	28 Sep 2020 18:26:40
User entered 'Yes (Y)'	System	28 Sep 2020 18:26:40

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:26:24', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '4a796469-09c1-47e8-934f-415ed1ef31a7'	System	28 Sep 2020 18:26:40
User entered '97.5'	System	28 Sep 2020 18:26:40

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:26:30', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '4a796469-09c1-47e8-934f-415ed1ef31a7'	System	28 Sep 2020 18:26:40
User entered 'No (N)'	System	28 Sep 2020 18:26:40

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:26:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '4a796469-09c1-47e8-934f-415ed1ef31a7'	System	28 Sep 2020 18:26:40
User entered '28 Sep 2020 14:26'	System	28 Sep 2020 18:26:40

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 6'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:02:09', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b8e2b75b-2110-40c2-8f53-0cbdb1b7ce72'	System	29 Sep 2020 16:03:06
User entered 'Yes (Y)'	System	29 Sep 2020 16:03:06

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:02:15', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b8e2b75b-2110-40c2-8f53-0cbdb1b7ce72'	System	29 Sep 2020 16:03:06
User entered '97.5'	System	29 Sep 2020 16:03:06

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:02:20', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b8e2b75b-2110-40c2-8f53-0cbdb1b7ce72'	System	29 Sep 2020 16:03:06
User entered 'No (N)'	System	29 Sep 2020 16:03:06

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:02:24', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'b8e2b75b-2110-40c2-8f53-0cbdb1b7ce72'	System	29 Sep 2020 16:03:06
User entered '29 Sep 2020 12:02'	System	29 Sep 2020 16:03:06

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 7'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T13:59:04', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6ff7e3ea-b8ac-4b9f-971d-54d3fab871c4'	System	30 Sep 2020 17:59:20
User entered 'Yes (Y)'	System	30 Sep 2020 17:59:20

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T13:59:10', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6ff7e3ea-b8ac-4b9f-971d-54d3fab871c4' User entered '97.5'	System	30 Sep 2020 17:59:20
	System	30 Sep 2020 17:59:20

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T13:59:15', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6ff7e3ea-b8ac-4b9f-971d-54d3fab871c4'	System	30 Sep 2020 17:59:20
User entered 'No (N)'	System	30 Sep 2020 17:59:20

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T13:59:18', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '6ff7e3ea-b8ac-4b9f-971d-54d3fab871c4'	System	30 Sep 2020 17:59:20
User entered '30 Sep 2020 13:59'	System	30 Sep 2020 17:59:20

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:47:20', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7e9bc16d-574d-4eee-9fbe-499baa07ab1b'	System	24 Sep 2020 14:48:20
User entered 'None (1)'	System	24 Sep 2020 14:48:20

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:47:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7e9bc16d-574d-4eee-9fbe-499baa07ab1b'	System	24 Sep 2020 14:48:20
User entered 'No (N)'	System	24 Sep 2020 14:48:20

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:47:51', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7e9bc16d-574d-4eee-9fbe-499baa07ab1b'	System	24 Sep 2020 14:48:20
User entered 'No (N)'	System	24 Sep 2020 14:48:20

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:48:08', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7e9bc16d-574d-4eee-9fbe-499baa07ab1b'	System	24 Sep 2020 14:48:20
User entered 'None (1)'	System	24 Sep 2020 14:48:20

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:48:14', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7e9bc16d-574d-4eee-9fbe-499baa07ab1b'	System	24 Sep 2020 14:48:20
User entered '24 Sep 2020 10:48'	System	24 Sep 2020 14:48:20

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Sep 2020 10:26'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Sep 2020 12:56'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:24:02', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '285892af-c696-4e92-a2f8-443a221fc7c3'	System	24 Sep 2020 19:25:12
User entered 'None (1)'	System	24 Sep 2020 19:25:12

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:24:12', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '285892af-c696-4e92-a2f8-443a221fc7c3'	System	24 Sep 2020 19:25:12
User entered 'No (N)'	System	24 Sep 2020 19:25:12

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:24:16', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '285892af-c696-4e92-a2f8-443a221fc7c3'	System	24 Sep 2020 19:25:12
User entered 'No (N)'	System	24 Sep 2020 19:25:12

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:24:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '285892af-c696-4e92-a2f8-443a221fc7c3'	System	24 Sep 2020 19:25:12
User entered 'None (1)'	System	24 Sep 2020 19:25:12

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:24:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '285892af-c696-4e92-a2f8-443a221fc7c3'	System	24 Sep 2020 19:25:12
User entered '24 Sep 2020 15:24'	System	24 Sep 2020 19:25:12

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Sep 2020 13:51'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 2'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:39:40', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9f1c8875-cd7f-40d1-a051-9b75f2ae32bf'	System	25 Sep 2020 17:40:05
User entered 'None (1)'	System	25 Sep 2020 17:40:05

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:39:44', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9f1c8875-cd7f-40d1-a051-9b75f2ae32bf'	System	25 Sep 2020 17:40:05
User entered 'No (N)'	System	25 Sep 2020 17:40:05

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:39:49', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9f1c8875-cd7f-40d1-a051-9b75f2ae32bf'	System	25 Sep 2020 17:40:05
User entered 'No (N)'	System	25 Sep 2020 17:40:05

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:39:54', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9f1c8875-cd7f-40d1-a051-9b75f2ae32bf'	System	25 Sep 2020 17:40:05
User entered 'None (1)'	System	25 Sep 2020 17:40:05

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:39:59', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '9f1c8875-cd7f-40d1-a051-9b75f2ae32bf'	System	25 Sep 2020 17:40:05
User entered '25 Sep 2020 13:39'	System	25 Sep 2020 17:40:05

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 3'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:01:32', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '99940118-86f0-4704-beb3-2e359566a7da'	System	26 Sep 2020 16:02:59
User entered 'None (1)'	System	26 Sep 2020 16:02:59

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:01:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '99940118-86f0-4704-beb3-2e359566a7da'	System	26 Sep 2020 16:02:59
User entered 'No (N)'	System	26 Sep 2020 16:02:59

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:01:40', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '99940118-86f0-4704-beb3-2e359566a7da'	System	26 Sep 2020 16:02:59
User entered 'No (N)'	System	26 Sep 2020 16:02:59

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:01:53', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '99940118-86f0-4704-beb3-2e359566a7da'	System	26 Sep 2020 16:02:59
User entered 'None (1)'	System	26 Sep 2020 16:02:59

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:01:58', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '99940118-86f0-4704-beb3-2e359566a7da'	System	26 Sep 2020 16:02:59
User entered '26 Sep 2020 12:01'	System	26 Sep 2020 16:02:59

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 4'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:08:51', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '45a4ade2-d770-4950-8ed2-00cd8e371064'	System	27 Sep 2020 16:09:16
User entered 'None (1)'	System	27 Sep 2020 16:09:16

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:08:55', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '45a4ade2-d770-4950-8ed2-00cd8e371064'	System	27 Sep 2020 16:09:16
User entered 'No (N)'	System	27 Sep 2020 16:09:16

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:08:59', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '45a4ade2-d770-4950-8ed2-00cd8e371064'	System	27 Sep 2020 16:09:16
User entered 'No (N)'	System	27 Sep 2020 16:09:16

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:09:09', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '45a4ade2-d770-4950-8ed2-00cd8e371064'	System	27 Sep 2020 16:09:16
User entered 'None (1)'	System	27 Sep 2020 16:09:16

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:09:13', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '45a4ade2-d770-4950-8ed2-00cd8e371064'	System	27 Sep 2020 16:09:16
User entered '27 Sep 2020 12:09'	System	27 Sep 2020 16:09:16

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 5'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:27:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '07d0299a-024b-4f6e-b10a-146a799acf75'	System	28 Sep 2020 18:27:28
User entered 'None (1)'	System	28 Sep 2020 18:27:28

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:27:06', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '07d0299a-024b-4f6e-b10a-146a799acf75'	System	28 Sep 2020 18:27:28
User entered 'No (N)'	System	28 Sep 2020 18:27:28

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:27:10', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '07d0299a-024b-4f6e-b10a-146a799acf75'	System	28 Sep 2020 18:27:28
User entered 'No (N)'	System	28 Sep 2020 18:27:28

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:27:19', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '07d0299a-024b-4f6e-b10a-146a799acf75'	System	28 Sep 2020 18:27:28
User entered 'None (1)'	System	28 Sep 2020 18:27:28

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:27:25', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '07d0299a-024b-4f6e-b10a-146a799acf75'	System	28 Sep 2020 18:27:28
User entered '28 Sep 2020 14:27'	System	28 Sep 2020 18:27:28

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 6'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:02:30', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7ced3321-3d10-42f4-b8c7-45fc2d31a2d6'	System	29 Sep 2020 16:03:28
User entered 'None (1)'	System	29 Sep 2020 16:03:28

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:02:35', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7ced3321-3d10-42f4-b8c7-45fc2d31a2d6'	System	29 Sep 2020 16:03:28
User entered 'No (N)'	System	29 Sep 2020 16:03:28

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:02:40', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7ced3321-3d10-42f4-b8c7-45fc2d31a2d6'	System	29 Sep 2020 16:03:28
User entered 'No (N)'	System	29 Sep 2020 16:03:28

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:02:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7ced3321-3d10-42f4-b8c7-45fc2d31a2d6'	System	29 Sep 2020 16:03:28
User entered 'None (1)'	System	29 Sep 2020 16:03:28

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:02:51', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7ced3321-3d10-42f4-b8c7-45fc2d31a2d6'	System	29 Sep 2020 16:03:28
User entered '29 Sep 2020 12:02'	System	29 Sep 2020 16:03:28

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 7'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T13:59:24', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '4e9f7ca2-d3d5-4696-87ec-282cd5d5e031'	System	30 Sep 2020 17:59:53
User entered 'None (1)'	System	30 Sep 2020 17:59:53

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T13:59:28', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '4e9f7ca2-d3d5-4696-87ec-282cd5d5e031'	System	30 Sep 2020 17:59:53
User entered 'No (N)'	System	30 Sep 2020 17:59:53

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T13:59:33', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '4e9f7ca2-d3d5-4696-87ec-282cd5d5e031'	System	30 Sep 2020 17:59:53
User entered 'No (N)'	System	30 Sep 2020 17:59:53

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T13:59:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '4e9f7ca2-d3d5-4696-87ec-282cd5d5e031'	System	30 Sep 2020 17:59:53
User entered 'None (1)'	System	30 Sep 2020 17:59:53

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T13:59:41', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '4e9f7ca2-d3d5-4696-87ec-282cd5d5e031'	System	30 Sep 2020 17:59:53
User entered '30 Sep 2020 13:59'	System	30 Sep 2020 17:59:53

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:48:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '776fa585-ce13-4cb9-8138-606bb834fa2d'	System	24 Sep 2020 14:49:03
User entered 'No interference with activity (1)'	System	24 Sep 2020 14:49:03

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:48:31', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '776fa585-ce13-4cb9-8138-606bb834fa2d'	System	24 Sep 2020 14:49:03
User entered 'None (0)'	System	24 Sep 2020 14:49:03

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:48:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '776fa585-ce13-4cb9-8138-606bb834fa2d'	System	24 Sep 2020 14:49:03
User entered 'None (0)'	System	24 Sep 2020 14:49:03

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:48:38', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '776fa585-ce13-4cb9-8138-606bb834fa2d'	System	24 Sep 2020 14:49:03
User entered 'None (0)'	System	24 Sep 2020 14:49:03

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:48:42', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '776fa585-ce13-4cb9-8138-606bb834fa2d'	System	24 Sep 2020 14:49:03
User entered 'None (0)'	System	24 Sep 2020 14:49:03

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:48:45', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '776fa585-ce13-4cb9-8138-606bb834fa2d'	System	24 Sep 2020 14:49:03
User entered 'None (0)'	System	24 Sep 2020 14:49:03

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:48:48', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '776fa585-ce13-4cb9-8138-606bb834fa2d'	System	24 Sep 2020 14:49:03
User entered 'No (N)'	System	24 Sep 2020 14:49:03

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T10:48:54', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '776fa585-ce13-4cb9-8138-606bb834fa2d'	System	24 Sep 2020 14:49:03
User entered '24 Sep 2020 10:48'	System	24 Sep 2020 14:49:03

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Sep 2020 10:26'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Sep 2020 12:56'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:24:44', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '646bf9f3-5a6d-4d6c-bbed-8a601ebca062'	System	24 Sep 2020 19:26:10
User entered 'None (0)'	System	24 Sep 2020 19:26:10

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:24:47', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '646bf9f3-5a6d-4d6c-bbed-8a601ebca062'	System	24 Sep 2020 19:26:10
User entered 'None (0)'	System	24 Sep 2020 19:26:10

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:24:51', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '646bf9f3-5a6d-4d6c-bbed-8a601ebca062'	System	24 Sep 2020 19:26:10
User entered 'None (0)'	System	24 Sep 2020 19:26:10

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:24:54', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '646bf9f3-5a6d-4d6c-bbed-8a601ebca062'	System	24 Sep 2020 19:26:10
User entered 'None (0)'	System	24 Sep 2020 19:26:10

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:24:57', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '646bf9f3-5a6d-4d6c-bbed-8a601ebca062'	System	24 Sep 2020 19:26:10
User entered 'None (0)'	System	24 Sep 2020 19:26:10

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:25:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '646bf9f3-5a6d-4d6c-bbed-8a601ebca062'	System	24 Sep 2020 19:26:10
User entered 'None (0)'	System	24 Sep 2020 19:26:10

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:25:07', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '646bf9f3-5a6d-4d6c-bbed-8a601ebca062'	System	24 Sep 2020 19:26:10
User entered 'No (N)'	System	24 Sep 2020 19:26:10

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-24T15:25:12', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '646bf9f3-5a6d-4d6c-bbed-8a601ebca062'	System	24 Sep 2020 19:26:10
User entered '24 Sep 2020 15:25'	System	24 Sep 2020 19:26:10

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '24 Sep 2020 13:51'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 2'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:40:08', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cac2b587-a3da-45e4-bbe0-804403b88e5f'	System	25 Sep 2020 17:40:42
User entered 'None (0)'	System	25 Sep 2020 17:40:42

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:40:15', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cac2b587-a3da-45e4-bbe0-804403b88e5f'	System	25 Sep 2020 17:40:42
User entered 'None (0)'	System	25 Sep 2020 17:40:42

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:40:19', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cac2b587-a3da-45e4-bbe0-804403b88e5f' User entered 'None (0)'	System	25 Sep 2020 17:40:42
	System	25 Sep 2020 17:40:42

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:40:23', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cac2b587-a3da-45e4-bbe0-804403b88e5f' User entered 'None (0)'	System	25 Sep 2020 17:40:42
	System	25 Sep 2020 17:40:42

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:40:27', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cac2b587-a3da-45e4-bbe0-804403b88e5f'	System	25 Sep 2020 17:40:42
User entered 'None (0)'	System	25 Sep 2020 17:40:42

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:40:30', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cac2b587-a3da-45e4-bbe0-804403b88e5f'	System	25 Sep 2020 17:40:42
User entered 'None (0)'	System	25 Sep 2020 17:40:42

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:40:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cac2b587-a3da-45e4-bbe0-804403b88e5f'	System	25 Sep 2020 17:40:42
User entered 'No (N)'	System	25 Sep 2020 17:40:42

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-25T13:40:39', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'cac2b587-a3da-45e4-bbe0-804403b88e5f'	System	25 Sep 2020 17:40:42
User entered '25 Sep 2020 13:40'	System	25 Sep 2020 17:40:42

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 3'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:02:04', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '769f7102-d71f-4564-a0b4-9cc1eca6628a' User entered 'None (0)'	System	26 Sep 2020 16:03:25
	System	26 Sep 2020 16:03:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:02:07', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '769f7102-d71f-4564-a0b4-9cc1eca6628a'	System	26 Sep 2020 16:03:25
User entered 'None (0)'	System	26 Sep 2020 16:03:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:02:10', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '769f7102-d71f-4564-a0b4-9cc1eca6628a'	System	26 Sep 2020 16:03:25
User entered 'None (0)'	System	26 Sep 2020 16:03:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:02:12', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '769f7102-d71f-4564-a0b4-9cc1eca6628a'	System	26 Sep 2020 16:03:25
User entered 'None (0)'	System	26 Sep 2020 16:03:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:02:16', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '769f7102-d71f-4564-a0b4-9cc1eca6628a'	System	26 Sep 2020 16:03:25
User entered 'None (0)'	System	26 Sep 2020 16:03:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:02:19', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '769f7102-d71f-4564-a0b4-9cc1eca6628a'	System	26 Sep 2020 16:03:25
User entered 'None (0)'	System	26 Sep 2020 16:03:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:02:22', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '769f7102-d71f-4564-a0b4-9cc1eca6628a'	System	26 Sep 2020 16:03:25
User entered 'No (N)'	System	26 Sep 2020 16:03:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-26T12:02:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '769f7102-d71f-4564-a0b4-9cc1eca6628a'	System	26 Sep 2020 16:03:25
User entered '26 Sep 2020 12:02'	System	26 Sep 2020 16:03:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 4'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:09:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '90c607af-88c8-4e13-8fda-15f302a6303f'	System	27 Sep 2020 16:09:50
User entered 'None (0)'	System	27 Sep 2020 16:09:50

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:09:20', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '90c607af-88c8-4e13-8fda-15f302a6303f'	System	27 Sep 2020 16:09:50
User entered 'None (0)'	System	27 Sep 2020 16:09:50

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:09:24', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '90c607af-88c8-4e13-8fda-15f302a6303f'	System	27 Sep 2020 16:09:50
User entered 'None (0)'	System	27 Sep 2020 16:09:50

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:09:29', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '90c607af-88c8-4e13-8fda-15f302a6303f'	System	27 Sep 2020 16:09:50
User entered 'None (0)'	System	27 Sep 2020 16:09:50

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:09:32', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '90c607af-88c8-4e13-8fda-15f302a6303f'	System	27 Sep 2020 16:09:50
User entered 'None (0)'	System	27 Sep 2020 16:09:50

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:09:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '90c607af-88c8-4e13-8fda-15f302a6303f'	System	27 Sep 2020 16:09:50
User entered 'None (0)'	System	27 Sep 2020 16:09:50

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:09:43', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '90c607af-88c8-4e13-8fda-15f302a6303f'	System	27 Sep 2020 16:09:50
User entered 'No (N)'	System	27 Sep 2020 16:09:50

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-27T12:09:47', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '90c607af-88c8-4e13-8fda-15f302a6303f'	System	27 Sep 2020 16:09:50
User entered '27 Sep 2020 12:09'	System	27 Sep 2020 16:09:50

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 5'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:27:30', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7f4a112b-5b6f-45e5-a5e9-e58ce0f1bc29'	System	28 Sep 2020 18:28:01
User entered 'None (0)'	System	28 Sep 2020 18:28:01

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:27:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7f4a112b-5b6f-45e5-a5e9-e58ce0f1bc29'	System	28 Sep 2020 18:28:01
User entered 'None (0)'	System	28 Sep 2020 18:28:01

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:27:37', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7f4a112b-5b6f-45e5-a5e9-e58ce0f1bc29'	System	28 Sep 2020 18:28:01
User entered 'None (0)'	System	28 Sep 2020 18:28:01

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:27:40', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7f4a112b-5b6f-45e5-a5e9-e58ce0f1bc29'	System	28 Sep 2020 18:28:01
User entered 'None (0)'	System	28 Sep 2020 18:28:01

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:27:43', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7f4a112b-5b6f-45e5-a5e9-e58ce0f1bc29'	System	28 Sep 2020 18:28:01
User entered 'None (0)'	System	28 Sep 2020 18:28:01

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:27:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7f4a112b-5b6f-45e5-a5e9-e58ce0f1bc29'	System	28 Sep 2020 18:28:01
User entered 'None (0)'	System	28 Sep 2020 18:28:01

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:27:51', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7f4a112b-5b6f-45e5-a5e9-e58ce0f1bc29'	System	28 Sep 2020 18:28:01
User entered 'No (N)'	System	28 Sep 2020 18:28:01

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-28T14:27:57', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7f4a112b-5b6f-45e5-a5e9-e58ce0f1bc29'	System	28 Sep 2020 18:28:01
User entered '28 Sep 2020 14:27'	System	28 Sep 2020 18:28:01

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 6'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:02:55', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e08ca330-0b84-4ff1-8fd5-12424bb41e47'	System	29 Sep 2020 16:03:54
User entered 'None (0)'	System	29 Sep 2020 16:03:54

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:02:59', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e08ca330-0b84-4ff1-8fd5-12424bb41e47'	System	29 Sep 2020 16:03:54
User entered 'None (0)'	System	29 Sep 2020 16:03:54

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:03:03', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e08ca330-0b84-4ff1-8fd5-12424bb41e47'	System	29 Sep 2020 16:03:54
User entered 'None (0)'	System	29 Sep 2020 16:03:54

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:03:07', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e08ca330-0b84-4ff1-8fd5-12424bb41e47'	System	29 Sep 2020 16:03:54
User entered 'None (0)'	System	29 Sep 2020 16:03:54

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:03:11', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e08ca330-0b84-4ff1-8fd5-12424bb41e47'	System	29 Sep 2020 16:03:54
User entered 'None (0)'	System	29 Sep 2020 16:03:54

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:03:14', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e08ca330-0b84-4ff1-8fd5-12424bb41e47'	System	29 Sep 2020 16:03:54
User entered 'None (0)'	System	29 Sep 2020 16:03:54

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:03:20', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e08ca330-0b84-4ff1-8fd5-12424bb41e47'	System	29 Sep 2020 16:03:54
User entered 'No (N)'	System	29 Sep 2020 16:03:54

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-29T12:03:25', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e08ca330-0b84-4ff1-8fd5-12424bb41e47'	System	29 Sep 2020 16:03:54
User entered '29 Sep 2020 12:03'	System	29 Sep 2020 16:03:54

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	24 Sep 2020 14:18:25
User entered 'Day 7'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T13:59:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5b052ff5-da97-4777-b081-6a8d888cdc6a'	System	30 Sep 2020 18:00:15
User entered 'None (0)'	System	30 Sep 2020 18:00:15

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T13:59:48', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5b052ff5-da97-4777-b081-6a8d888cdc6a'	System	30 Sep 2020 18:00:15
User entered 'None (0)'	System	30 Sep 2020 18:00:15

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T13:59:51', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5b052ff5-da97-4777-b081-6a8d888cdc6a'	System	30 Sep 2020 18:00:15
User entered 'None (0)'	System	30 Sep 2020 18:00:15

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T13:59:55', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5b052ff5-da97-4777-b081-6a8d888cdc6a'	System	30 Sep 2020 18:00:15
User entered 'None (0)'	System	30 Sep 2020 18:00:15

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T13:59:59', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5b052ff5-da97-4777-b081-6a8d888cdc6a'	System	30 Sep 2020 18:00:15
User entered 'None (0)'	System	30 Sep 2020 18:00:15

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T14:00:01', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5b052ff5-da97-4777-b081-6a8d888cdc6a'	System	30 Sep 2020 18:00:15
User entered 'None (0)'	System	30 Sep 2020 18:00:15

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T14:00:08', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5b052ff5-da97-4777-b081-6a8d888cdc6a'	System	30 Sep 2020 18:00:15
User entered 'No (N)'	System	30 Sep 2020 18:00:15

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-09-30T14:00:12', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5b052ff5-da97-4777-b081-6a8d888cdc6a'	System	30 Sep 2020 18:00:15
User entered '30 Sep 2020 14:00'	System	30 Sep 2020 18:00:15

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 14:18:25

US3202191

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:41:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 14:18:25

US3202191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	01 Oct 2020 13:40:50

US3202191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '1 Oct 2020'	(b) (4) Lilian Nukuna (b) (4)	01 Oct 2020 13:40:50

US3202191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	01 Oct 2020 13:40:50

US3202191

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	Lilian Nukuna (b) (4)	01 Oct 2020 13:40:50

US3202191

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	01 Oct 2020 13:40:56

US3202191

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'I'	System	01 Oct 2020 13:40:56

US3202191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	09 Oct 2020 21:44:04

US3202191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '9 Oct 2020'	(b) (4) Lilian Nukuna (b) (4)	09 Oct 2020 21:44:04

US3202191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	09 Oct 2020 21:44:04

US3202191

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	Lilian Nukuna (b) (4)	09 Oct 2020 21:44:04

US3202191

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	09 Oct 2020 21:44:10

US3202191

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'I'	System	09 Oct 2020 21:44:10

US3202191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	15 Oct 2020 14:16:38

US3202191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Lilian Nukuna (b) (4)	16 Oct 2020 14:30:49
User entered '15 Oct 2020'	(b) (4)	
	Lilian Nukuna (b) (4)	15 Oct 2020 14:16:38
	(b) (4)	

US3202191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	15 Oct 2020 14:16:38

US3202191

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered empty.	Lilian Nukuna (b) (4)	15 Oct 2020 14:16:38

US3202191

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:02
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	15 Oct 2020 14:16:43

US3202191

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'I'	System	15 Oct 2020 14:16:43

US3202191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:35:48

US3202191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '23 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:35:48

US3202191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:35:48

US3202191

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'VISIT3'	System	26 Oct 2020 15:35:48

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '23 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '09:55'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered '23 Oct 2020 09:55'	System	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '98.2' F	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '61'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'bpm'	System	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '18'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'breaths/min'	System	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '129'	(b) (4) Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'mmHg'	System	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '82'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'mmHg'	System	26 Oct 2020 15:36:22

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46

US3202191

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46

US3202191

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:36:56

US3202191

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:36:56

US3202191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:37:23

US3202191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '23 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:37:23

US3202191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered '10:01'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:37:23

US3202191

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered '23 Oct 2020 10:01'	System	26 Oct 2020 15:37:23

US3202191

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:11:07
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	26 Oct 2020 15:37:30

US3202191

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'I'	System	26 Oct 2020 15:37:30

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 64'	System	14 Aug 2020 17:26:21

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-10-14T05:17:49', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5d19624b-c238-4778-a86c-9c7cf62df9f1'	System	14 Oct 2020 09:18:09
User entered 'No (N)'	System	14 Oct 2020 09:18:09

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-10-14T05:18:00', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5d19624b-c238-4778-a86c-9c7cf62df9f1'	System	14 Oct 2020 09:18:09
User entered 'No (N)'	System	14 Oct 2020 09:18:09

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-10-14T05:18:05', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '5d19624b-c238-4778-a86c-9c7cf62df9f1'	System	14 Oct 2020 09:18:09
User entered '14 Oct 2020 05:18:05'	System	14 Oct 2020 09:18:09

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 17:26:21

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 71'	System	14 Aug 2020 17:26:21

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-10-21T06:40:43', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '727422a7-1fb3-4e5f-82b0-001015e2d48c'	System	21 Oct 2020 10:41:58
User entered 'Yes (Y)'	System	21 Oct 2020 10:41:58

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-10-21T06:40:49', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '727422a7-1fb3-4e5f-82b0-001015e2d48c'	System	21 Oct 2020 10:41:58
User entered 'No (N)'	System	21 Oct 2020 10:41:58

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-10-21T06:40:56', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '727422a7-1fb3-4e5f-82b0-001015e2d48c'	System	21 Oct 2020 10:41:58
User entered 'No (N)'	System	21 Oct 2020 10:41:58

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-10-21T06:41:11', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '727422a7-1fb3-4e5f-82b0-001015e2d48c'	System	21 Oct 2020 10:41:58
User entered 'Yes (Y)'	System	21 Oct 2020 10:41:58

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-10-21T06:41:23', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '727422a7-1fb3-4e5f-82b0-001015e2d48c'	System	21 Oct 2020 10:41:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Oct 2020 10:41:58

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-10-21T06:41:39', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '727422a7-1fb3-4e5f-82b0-001015e2d48c'	System	21 Oct 2020 10:41:58
User entered '21 Oct 2020 06:41:39'	System	21 Oct 2020 10:41:58

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 17:26:21

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:36:37
Data entry locked.	System	14 Aug 2020 17:26:21
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 78'	System	14 Aug 2020 17:26:21

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Have you been exposed to someone with 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 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39
Data entry locked.	System	14 Aug 2020 17:26:21
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 17:26:21

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39
Data entry locked.	System	14 Aug 2020 17:26:21
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 92'	System	14 Aug 2020 17:26:21

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Have you been exposed to someone with 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 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3202191

Folder: Safety Follow Up Diary (1)

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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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39
Data entry locked.	System	14 Aug 2020 17:26:21
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 17:26:21

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39
Data entry locked.	System	14 Aug 2020 17:26:21
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39
Data entry locked.	System	14 Aug 2020 17:26:21
User entered 'Day 99'	System	14 Aug 2020 17:26:21

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Have you been exposed to someone with 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 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: 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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39
Data entry locked.	System	14 Aug 2020 17:26:21
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 17:26:21

US3202191

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:32:39
Data entry locked.	System	14 Aug 2020 17:26:21
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 17:26:21

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2020-11-19T14:28:22', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '80d41e27-4560-4946-bf6e-cfeec7913aa4'	System	19 Nov 2020 19:29:16
User entered 'Yes (Y)'	System	19 Nov 2020 19:29:16

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2020-11-19T14:28:29', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '80d41e27-4560-4946-bf6e-cfeec7913aa4'	System	19 Nov 2020 19:29:16
User entered 'No (N)'	System	19 Nov 2020 19:29:16

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-11-19T14:28:36', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '80d41e27-4560-4946-bf6e-cfeec7913aa4'	System	19 Nov 2020 19:29:16
User entered 'No (N)'	System	19 Nov 2020 19:29:16

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-11-19T14:28:44', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '80d41e27-4560-4946-bf6e-cfeec7913aa4'	System	19 Nov 2020 19:29:16
User entered 'Yes (Y)'	System	19 Nov 2020 19:29:16

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-11-19T14:28:51', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '80d41e27-4560-4946-bf6e-cfeec7913aa4'	System	19 Nov 2020 19:29:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 19:29:16

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-11-19T14:29:01', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '80d41e27-4560-4946-bf6e-cfeec7913aa4'	System	19 Nov 2020 19:29:16
User entered '19 Nov 2020 14:29:01'	System	19 Nov 2020 19:29:16

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2020-11-22T08:18:53', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '87491d34-41d8-4a99-899f-665b1b786424'	System	22 Nov 2020 13:19:05
User entered 'No (N)'	System	22 Nov 2020 13:19:05

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2020-11-22T08:18:59', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '87491d34-41d8-4a99-899f-665b1b786424'	System	22 Nov 2020 13:19:05
User entered 'No (N)'	System	22 Nov 2020 13:19:05

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-11-22T08:19:03', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '87491d34-41d8-4a99-899f-665b1b786424'	System	22 Nov 2020 13:19:05
User entered '22 Nov 2020 08:19:03'	System	22 Nov 2020 13:19:05

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2020-12-16T18:47:49', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ff1678a4-7198-42ef-8d7f-82894245dfe1'	System	16 Dec 2020 23:48:07
User entered 'No (N)'	System	16 Dec 2020 23:48:07

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2020-12-16T18:47:55', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ff1678a4-7198-42ef-8d7f-82894245dfe1'	System	16 Dec 2020 23:48:07
User entered 'No (N)'	System	16 Dec 2020 23:48:07

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-12-16T18:48:01', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ff1678a4-7198-42ef-8d7f-82894245dfe1' User entered '16 Dec 2020 18:48:01'	System	16 Dec 2020 23:48:07
	System	16 Dec 2020 23:48:07

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2020-12-20T03:59:15', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'd1efc2fa-5064-40b1-b88f-495fc38269b7'	System	20 Dec 2020 08:59:42
User entered 'No (N)'	System	20 Dec 2020 08:59:42

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2020-12-20T03:59:30', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'd1efc2fa-5064-40b1-b88f-495fc38269b7'	System	20 Dec 2020 08:59:42
User entered 'No (N)'	System	20 Dec 2020 08:59:42

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2020-12-20T03:59:38', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'd1efc2fa-5064-40b1-b88f-495fc38269b7'	System	20 Dec 2020 08:59:42
User entered '20 Dec 2020 03:59:38'	System	20 Dec 2020 08:59:42

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2021-01-24T06:46:02', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c281d320-2004-406c-b90e-586db942bee1'	System	24 Jan 2021 11:46:27
User entered 'No (N)'	System	24 Jan 2021 11:46:27

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2021-01-24T06:46:10', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c281d320-2004-406c-b90e-586db942bee1'	System	24 Jan 2021 11:46:27
User entered 'No (N)'	System	24 Jan 2021 11:46:27

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-01-24T06:46:24', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c281d320-2004-406c-b90e-586db942bee1' User entered '24 Jan 2021 06:46:24'	System	24 Jan 2021 11:46:27
	System	24 Jan 2021 11:46:27

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2021-01-31T09:23:35', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'f98e0378-44bb-4f48-ad17-bc30904353fb'	System	31 Jan 2021 14:23:50
User entered 'No (N)'	System	31 Jan 2021 14:23:50

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2021-01-31T09:23:41', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'f98e0378-44bb-4f48-ad17-bc30904353fb'	System	31 Jan 2021 14:23:50
User entered 'No (N)'	System	31 Jan 2021 14:23:50

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-01-31T09:23:48', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'f98e0378-44bb-4f48-ad17-bc30904353fb' User entered '31 Jan 2021 09:23:48'	System	31 Jan 2021 14:23:50
	System	31 Jan 2021 14:23:50

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2021-02-07T10:03:52', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '075c7c54-ac32-4961-b5b8-df2db759a9ed'	System	07 Feb 2021 15:04:10
User entered 'No (N)'	System	07 Feb 2021 15:04:10

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2021-02-07T10:03:59', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '075c7c54-ac32-4961-b5b8-df2db759a9ed'	System	07 Feb 2021 15:04:10
User entered 'No (N)'	System	07 Feb 2021 15:04:10

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-02-07T10:04:07', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '075c7c54-ac32-4961-b5b8-df2db759a9ed'	System	07 Feb 2021 15:04:10
User entered '07 Feb 2021 10:04:07'	System	07 Feb 2021 15:04:10

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2021-02-14T06:21:57', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'f0df933d-fdbf-4a74-8d00-04ec0dfea36a'	System	14 Feb 2021 11:22:19
User entered 'No (N)'	System	14 Feb 2021 11:22:19

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2021-02-14T06:22:13', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'f0df933d-fdbf-4a74-8d00-04ec0dfea36a'	System	14 Feb 2021 11:22:19
User entered 'No (N)'	System	14 Feb 2021 11:22:19

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-02-14T06:22:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'f0df933d-fdbf-4a74-8d00-04ec0dfea36a'	System	14 Feb 2021 11:22:19
User entered '14 Feb 2021 06:22:17'	System	14 Feb 2021 11:22:19

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2021-02-21T06:11:46', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ea4c3749-4086-41ce-b859-5fa4936ed8ba'	System	21 Feb 2021 11:11:59
User entered 'No (N)'	System	21 Feb 2021 11:11:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2021-02-21T06:11:53', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ea4c3749-4086-41ce-b859-5fa4936ed8ba'	System	21 Feb 2021 11:11:59
User entered 'No (N)'	System	21 Feb 2021 11:11:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-02-21T06:11:57', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ea4c3749-4086-41ce-b859-5fa4936ed8ba' User entered '21 Feb 2021 06:11:57'	System	21 Feb 2021 11:11:59
	System	21 Feb 2021 11:11:59

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2021-02-28T05:57:02', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '93480796-f39a-4580-9bf4-23afcf7ce386'	System	28 Feb 2021 10:57:20
User entered 'No (N)'	System	28 Feb 2021 10:57:20

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2021-02-28T05:57:08', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '93480796-f39a-4580-9bf4-23afcf7ce386'	System	28 Feb 2021 10:57:20
User entered 'No (N)'	System	28 Feb 2021 10:57:20

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-02-28T05:57:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '93480796-f39a-4580-9bf4-23afcf7ce386'	System	28 Feb 2021 10:57:20
User entered '28 Feb 2021 05:57:17'	System	28 Feb 2021 10:57:20

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2021-03-07T07:00:27', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '73fc7600-42de-4035-84d4-97649c269cc0'	System	07 Mar 2021 12:00:41
User entered 'No (N)'	System	07 Mar 2021 12:00:41

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2021-03-07T07:00:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '73fc7600-42de-4035-84d4-97649c269cc0'	System	07 Mar 2021 12:00:41
User entered 'No (N)'	System	07 Mar 2021 12:00:41

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-03-07T07:00:38', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '73fc7600-42de-4035-84d4-97649c269cc0'	System	07 Mar 2021 12:00:41
User entered '07 Mar 2021 07:00:38'	System	07 Mar 2021 12:00:41

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2021-03-14T07:15:58', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e630ebfb-7c74-4a85-9a71-5fc61a9dfa6e'	System	14 Mar 2021 11:16:13
User entered 'No (N)'	System	14 Mar 2021 11:16:13

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2021-03-14T07:16:04', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e630ebfb-7c74-4a85-9a71-5fc61a9dfa6e'	System	14 Mar 2021 11:16:13
User entered 'No (N)'	System	14 Mar 2021 11:16:13

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-03-14T07:16:08', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'e630ebfb-7c74-4a85-9a71-5fc61a9dfa6e'	System	14 Mar 2021 11:16:13
User entered '14 Mar 2021 07:16:08'	System	14 Mar 2021 11:16:13

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2021-03-21T06:42:42', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7a3190ce-ce92-485b-a0ae-9b89d4b35105'	System	21 Mar 2021 10:42:57
User entered 'No (N)'	System	21 Mar 2021 10:42:57

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2021-03-21T06:42:48', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7a3190ce-ce92-485b-a0ae-9b89d4b35105'	System	21 Mar 2021 10:42:57
User entered 'No (N)'	System	21 Mar 2021 10:42:57

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-03-21T06:42:51', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '7a3190ce-ce92-485b-a0ae-9b89d4b35105'	System	21 Mar 2021 10:42:57
User entered '21 Mar 2021 06:42:51'	System	21 Mar 2021 10:42:57

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2021-03-28T07:30:32', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '76cb2485-7067-45ad-a4c6-c0d1f88b0fdc'	System	28 Mar 2021 11:30:44
User entered 'No (N)'	System	28 Mar 2021 11:30:44

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2021-03-28T07:30:37', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '76cb2485-7067-45ad-a4c6-c0d1f88b0fdc'	System	28 Mar 2021 11:30:44
User entered 'No (N)'	System	28 Mar 2021 11:30:44

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-03-28T07:30:41', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '76cb2485-7067-45ad-a4c6-c0d1f88b0fdc'	System	28 Mar 2021 11:30:44
User entered '28 Mar 2021 07:30:41'	System	28 Mar 2021 11:30:44

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2021-04-04T12:12:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '0850cbee-c0a2-42de-86ef-1e0a55a1e0f9'	System	04 Apr 2021 16:12:45
User entered 'No (N)'	System	04 Apr 2021 16:12:45

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2021-04-04T12:12:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '0850cbee-c0a2-42de-86ef-1e0a55a1e0f9'	System	04 Apr 2021 16:12:45
User entered 'No (N)'	System	04 Apr 2021 16:12:45

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-04-04T12:12:29', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '0850cbee-c0a2-42de-86ef-1e0a55a1e0f9'	System	04 Apr 2021 16:12:45
User entered '04 Apr 2021 12:12:29'	System	04 Apr 2021 16:12:45

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2021-04-11T09:14:38', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ec83a084-77a7-4938-8deb-c66e00d572ff'	System	11 Apr 2021 13:14:51
User entered 'No (N)'	System	11 Apr 2021 13:14:51

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2021-04-11T09:14:44', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ec83a084-77a7-4938-8deb-c66e00d572ff'	System	11 Apr 2021 13:14:51
User entered 'No (N)'	System	11 Apr 2021 13:14:51

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-04-11T09:14:47', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'ec83a084-77a7-4938-8deb-c66e00d572ff' User entered '11 Apr 2021 09:14:47'	System	11 Apr 2021 13:14:51
	System	11 Apr 2021 13:14:51

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2021-04-18T06:15:17', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c0067feb-cef5-45c3-9a94-a6d5cc4f2570'	System	18 Apr 2021 10:15:28
User entered 'No (N)'	System	18 Apr 2021 10:15:28

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2021-04-18T06:15:22', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c0067feb-cef5-45c3-9a94-a6d5cc4f2570'	System	18 Apr 2021 10:15:28
User entered 'No (N)'	System	18 Apr 2021 10:15:28

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-04-18T06:15:25', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'c0067feb-cef5-45c3-9a94-a6d5cc4f2570'	System	18 Apr 2021 10:15:28
User entered '18 Apr 2021 06:15:25'	System	18 Apr 2021 10:15:28

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[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 (b5e3f2ef2ab43c18)', Time: '2021-04-25T07:14:14', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1f7d1b1a-957e-49f0-ba9e-b587d80c67d0'	System	25 Apr 2021 11:14:27
User entered 'No (N)'	System	25 Apr 2021 11:14:27

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

Have you been exposed to someone with 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 (b5e3f2ef2ab43c18)', Time: '2021-04-25T07:14:19', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1f7d1b1a-957e-49f0-ba9e-b587d80c67d0'	System	25 Apr 2021 11:14:27
User entered 'No (N)'	System	25 Apr 2021 11:14:27

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-04-25T07:14:23', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: '1f7d1b1a-957e-49f0-ba9e-b587d80c67d0'	System	25 Apr 2021 11:14:27
User entered '25 Apr 2021 07:14:23'	System	25 Apr 2021 11:14:27

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:32:39

US3202191

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:41:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:32:39
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:32:39

US3202191

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:41:09

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-02-28T05:57:26', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a62d18c0-ec50-4592-bac1-199c350ba4a3'	System	28 Feb 2021 10:57:36
User entered 'No (N)'	System	28 Feb 2021 10:57:36

US3202191

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:41:09

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:35:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b5e3f2ef2ab43c18)', Time: '2021-02-28T05:57:34', User OID: 'PatientReportedOutcome (US3202191)', ODM File OID: 'a62d18c0-ec50-4592-bac1-199c350ba4a3'	System	28 Feb 2021 10:57:36
User entered '28 Feb 2021 05:57:34'	System	28 Feb 2021 10:57:36

US3202191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:57
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 07:47:13
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	18 Feb 2021 17:28:25
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 19:46:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 18:31:17

US3202191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:57
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:31:17

US3202191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:57
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:21:51
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 18:37:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Nov 2020 18:31:17

US3202191

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:57
User entered 'LVM sub called back on 19 nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:21:46
User closed query 'The Contact Status is 'CONTACT System NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).		19 Nov 2020 18:37:24
User entered 'lvm' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 18:37:24
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	19 Nov 2020 18:37:13
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 18:31:17

US3202191

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:31:24

US3202191

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:46:46
User entered 'I'	System	19 Nov 2020 18:31:24

US3202191

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	07 Mar 2021 17:58:03

US3202191

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '23 Dec 2020'	(b) (4) zackery harmon (b) (4)	07 Mar 2021 17:58:03

US3202191

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	07 Mar 2021 17:58:03

US3202191

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) zackery harmon (b) (4)	07 Mar 2021 17:58:03
	(b) (4)	

US3202191

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	22 Jan 2021 21:23:37

US3202191

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User entered 'I'	System	22 Jan 2021 21:23:37

US3202191

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	22 Jan 2021 21:23:48

US3202191

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 06JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 09:59:08
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 06JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	18 Feb 2021 17:28:06
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 06JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 12:06:44
User entered '22 Jan 2021'	Lilian Nukuna (b) (4) (b) (4)	22 Jan 2021 21:23:48

US3202191

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	22 Jan 2021 21:23:48

US3202191

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	Lilian Nukuna (b) (4)	22 Jan 2021 21:23:48

US3202191

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	22 Jan 2021 21:23:54

US3202191

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User entered 'I'	System	22 Jan 2021 21:23:54

US3202191

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:40:42

US3202191

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:40:42

US3202191

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:40:42

US3202191

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:41:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 20:40:42

US3202191

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Sample dated 12Mar2021 is reported for Visit 4 Day209 in PPD Central lab: however, visit 4 Day 209 is blank in EDC. Please review and reconcile. Thanks. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 14:32:25
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Sample dated 12Mar2021 is reported for Visit 4 Day209 in PPD Central lab: however, visit 4 Day 209 is blank in EDC. Please review and reconcile. Thanks. ' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	07 Apr 2021 15:37:29
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Sample dated 12Mar2021 is reported for Visit 4 Day209 in PPD Central lab: however, visit 4 Day 209 is blank in EDC. Please review and reconcile. Thanks. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 05:18:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:40:47

US3202191

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:34
User entered 'I'	System	24 Feb 2021 20:40:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:40

US3202191

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '12 Mar 2021'	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:40

US3202191

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:40

US3202191

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User entered 'VISIT4'	System	07 Apr 2021 15:37:40

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User entered empty.	System	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User entered empty.	System	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User entered empty.	System	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User entered empty.	System	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User entered empty.	System	07 Apr 2021 15:37:47

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44

US3202191

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44

US3202191

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:52

US3202191

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:52

US3202191

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:38:14

US3202191

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '12 Mar 2021'	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:38:14

US3202191

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '10:49'	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:38:14

US3202191

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User entered '12 Mar 2021 10:49'	System	07 Apr 2021 15:38:14

US3202191

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	07 Apr 2021 15:37:57

US3202191

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:41:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:58:44
User entered 'I'	System	07 Apr 2021 15:37:57

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:41:09

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '28 Apr 2021'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:17:13

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:41:09

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '11:00'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:17:13

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:41:09

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Apr 2021 11:00'	System	30 Apr 2021 12:17:13

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:41:09

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	zackery harmon (b) (4)	30 Apr 2021 12:17:13

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:41:09

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:17:13

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Date](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 12:18:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 12:18:35
User entered '22 Apr 2021' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 12:17:19
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for zackery harmon change Data Entry Error	(b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Apr 2021 12:18:35
User entered empty.	System	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for zackery harmon change Data Entry Error	(b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:41:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:18:35
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:17:19

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Date](#)

Audit	User	Time (GMT)
User entered '23 Apr 2021'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:41:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:01

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Date](#)

Audit	User	Time (GMT)
User entered '23 Apr 2021'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:41:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:22:50
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Date](#)

Audit	User	Time (GMT)
User entered '24 Apr 2021'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for zackery harmon change Data Entry Error	(b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Apr 2021 12:26:12
User entered empty.	System	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for zackery harmon change Data Entry Error	(b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Per Query Resolution	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:41:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:26:12
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Date](#)

Audit	User	Time (GMT)
User entered '25 Apr 2021'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for zackery harmon change Data Entry Error	(b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Apr 2021 12:27:03
User entered empty.	System	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for zackery harmon change Data Entry Error	(b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:41:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:03
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Date](#)

Audit	User	Time (GMT)
User entered '26 Apr 2021'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:41:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:27:59
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Date](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

Temperature

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:41:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:28:41
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:21:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27
User entered 'Day 3 (Day 3)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Date](#)

Audit	User	Time (GMT)
User entered '28 Apr 2021' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:21:27
User entered '24 Apr 2021'	zackery harmon (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:53:50
User entered missing code ND - Not Done.	zackery harmon (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '36.9' C reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:53:50
User entered missing code ND - Not Done.	zackery harmon (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

Nasal Congestion

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:41:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:18

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:21:27
User entered 'Day 4 (Day 4)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Date](#)

Audit	User	Time (GMT)
User entered '29 Apr 2021' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:21:27
User entered '25 Apr 2021'	zackery harmon (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '100' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:54:15
User entered missing code ND - Not Done.	zackery harmon (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.5' F reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:54:15
User entered missing code ND - Not Done.	zackery harmon (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:54:21
User entered 'Mild (Mild)'	zackery harmon (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:41:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:19:56

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)' reason for change:	zackery harmon (b) (4)	30 Apr 2021 12:54:59
Data Entry Error	(b) (4)	
User entered 'Day 5 (Day 5)'	zackery harmon (b) (4)	30 Apr 2021 12:20:30
	(b) (4)	

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[Date](#)

Audit	User	Time (GMT)
User entered '30 Apr 2021' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:55:15
User entered '29 Apr 2021' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:54:59
User entered '26 Apr 2021'	zackery harmon (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '98' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:54:59
User entered missing code ND - Not Done.	zackery harmon (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[Temperature](#)

Audit	User	Time (GMT)
User entered '97.5' F reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:54:59
User entered missing code ND - Not Done.	zackery harmon (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

Fatigue

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Apr 2021 12:54:59
User entered 'Moderate (Moderate)'	zackery harmon (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

Nasal Congestion

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:41:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:20:30

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Teresa Deese (b) (4) [REDACTED] [REDACTED]	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Date](#)

Audit	User	Time (GMT)
User entered '1 May 2021'	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered 'I'	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

Fatigue

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

Nasal Congestion

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:41:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:46:50

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 12 (Day 12)'	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Date](#)

Audit	User	Time (GMT)
User entered '2 May 2021'	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered 'I'	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:41:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:04

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 13 (Day 13)'	Teresa Deese (b) (4) [REDACTED] [REDACTED]	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Date](#)

Audit	User	Time (GMT)
User entered '3 May 2021'	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered 'I'	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4) [REDACTED] [REDACTED]	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4) [REDACTED] [REDACTED]	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:41:09

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Teresa Deese (b) (4)	03 May 2021 13:47:22

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:09

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '28 Apr 2021'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:56:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:09

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:56:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:09

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 12:46:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 12:46:38
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	03 May 2021 12:46:38
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 12:56:27
User entered empty.	zackery harmon (b) (4)	30 Apr 2021 12:56:27
	(b) (4)	

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:09

[Date of Test](#)

Audit	User	Time (GMT)
User entered '28 Apr 2021'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:56:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:09

Type of Test Performed

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (Nasopharyngealzackery harmon Swab)'	(b) (4)	30 Apr 2021 12:56:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:09

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:56:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:09

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:56:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:09

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:56:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:09

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:56:27

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:41:09

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 May 2021 12:46:38

US3202191

Folder: Covid-19 Assessment 28 Apr 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:41:09

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:56:34

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:41:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:41:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:41:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '30 Apr 2021'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:41:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:41:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 12:47:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 12:47:09
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Erica Osmundsen (b) (4) [REDACTED]	03 May 2021 12:47:09
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 12:15:54
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:41:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:41:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:41:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 12:47:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 12:47:09
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Erica Osmundsen (b) (4) [REDACTED]	03 May 2021 12:47:09
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 12:15:54
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:41:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:41:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:41:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 12:47:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 12:47:09
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Erica Osmundsen (b) (4) [REDACTED]	03 May 2021 12:47:09
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 12:15:54
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:41:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:41:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:41:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 12:47:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 12:47:09
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Erica Osmundsen (b) (4) [REDACTED]	03 May 2021 12:47:09
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 12:15:54
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:41:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:41:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:41:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 12:47:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 12:47:09
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Erica Osmundsen (b) (4) [REDACTED]	03 May 2021 12:47:09
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 12:15:54
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:41:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:41:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:41:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 12:47:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 12:47:09
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Erica Osmundsen (b) (4) [REDACTED]	03 May 2021 12:47:09
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Apr 2021 12:15:54
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:41:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:54

US3202191

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:14:22

US3202191

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Apr 2021'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:14:22

US3202191

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:14:22

US3202191

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	30 Apr 2021 12:14:22

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Apr 2021'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:34'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Apr 2021 11:34'	System	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Height (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	zackery harmon (b) (4)	30 Apr 2021 12:15:28
DataPoint set to visible.	(b) (4) System	30 Apr 2021 12:14:22

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	zackery harmon (b) (4)	30 Apr 2021 12:15:28
DataPoint set to visible.	(b) (4) System	30 Apr 2021 12:14:22

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.9' C	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Respiratory Rate (xxx)

Audit	User	Time (GMT)
User entered '12'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '118'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '70'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:41:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Apr 2021 12:15:28

US3202191

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:09

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:34

US3202191

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:41:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Apr 2021'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:34

US3202191

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:41:09

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:44

US3202191

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:41:09

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '28 Apr 2021'	zackery harmon (b) (4) (b) (4)	30 Apr 2021 12:15:44

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:26:15

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '6 Jan 2021'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:26:15

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[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 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:26:15

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:41:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User entered 'UNBLND_DECIDE'	System	18 Feb 2021 17:26:15

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:09

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User closed query 'Per CDM: Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 10:15:02
Query 'Per CDM: Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' answered with 'date of consent version had been entered here in error' (Site from DM).	Erica Osmundsen (b) (4)	08 Apr 2021 21:55:44
User entered '06 Jan 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	08 Apr 2021 21:52:50
User opened query 'Per CDM: Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:57:04
User entered '24 Dec 2020'	Teresa Deese (b) (4)	18 Feb 2021 17:27:24

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:09

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:48:37

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:09

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:27:24

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:09

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:48:37

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:09

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '6 Jan 2021'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:27:24

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:09

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:27:24

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:09

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:27:24

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:09

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:27:24

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:09

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:27:24

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:09

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User entered empty.	System	18 Feb 2021 17:27:24

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:41:09

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User entered empty.	System	18 Feb 2021 17:27:24

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:27:42

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '6 Jan 2021'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:27:42

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '13:14'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:27:42

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:41:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User entered '6 Jan 2021 13:14'	System	18 Feb 2021 17:27:42

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:27:53

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:09

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '6 Jan 2021'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:27:53

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:09

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '13:10'	(b) (4) Teresa Deese (b) (4)	18 Feb 2021 17:27:53

US3202191

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:41:09

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:09
User entered '6 Jan 2021 13:10'	System	18 Feb 2021 17:27:53

US3202191

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:41:09

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:23
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 08:49:33
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, MUSCLE ACHES lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 08:49:31
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, JOINT ACHES lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 08:49:29
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	20 Apr 2021 14:42:56

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:41:09

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, MUSCLE ACHES lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	20 Apr 2021 14:42:41
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, JOINT ACHES lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	20 Apr 2021 14:42:28
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 06:49:28
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, MUSCLE ACHES lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 06:49:22

US3202191

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:41:09

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's DOSE 1 diary, JOINT ACHES lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 06:49:18
User closed query 'Per CDM: Response does not satisfy query. If AE is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 10:39:12
Query 'Per CDM: Response does not satisfy query. If AE is already recorded, please provide log line number.' answered with 'AEs are listed. look at dates' (Site from DM).	Teresa Deese (b) (4)	07 Apr 2021 15:36:41
User opened query 'Per CDM: Response does not satisfy query. If AE is already recorded, please provide log line number.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:28:42
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 96, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:28:42
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 96, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'go back & look at the AE list' (Site from DM).	Teresa Deese (b) (4)	30 Mar 2021 19:38:11

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:41:09

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 96, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 10:48:08
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:09:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:08:17
User closed query 'Orthopedic records of 02Dec2020= diagnosis of Cubital Tunnel Syndrome with Tardy Ulnar Nerve Palsy- please add as AE if appropriate' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 17:26:50
Query 'Orthopedic records of 02Dec2020= diagnosis of Cubital Tunnel Syndrome with Tardy Ulnar Nerve Palsy- please add as AE if appropriate' answered with 'updated' (Site from CRA).	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:33:18
User opened query 'Orthopedic records of 02Dec2020= diagnosis of Cubital Tunnel Syndrome with Tardy Ulnar Nerve Palsy- please add as AE if appropriate' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 20:54:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:37:38
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 14:19:06

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:18:17
Query 'per medical record notes this was Right Olecranon Bursitis, please verify' canceled (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:18:15
User opened query 'per medical record notes this was Right Olecranon Bursitis, please verify' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:17:03
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 16:15:58
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:53:48
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:52:43
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Laceration - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 17:04:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 17:04:23
Data point term sent to Coder	System	26 Oct 2020 15:39:35
User entered 'Laceration of right elbow'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:53:48
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:52:45
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:53:48
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:52:46
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:53:48
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:52:48
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:53:48
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:53:20
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '8 Oct 2020'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:53:48
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:53:22
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User entered empty.	System	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:10:11
User closed query 'source = resolved, please verify' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:10:09
Query 'source = resolved, please verify' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	28 Jan 2021 16:00:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	28 Jan 2021 15:59:58
User opened query 'source = resolved, please verify' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:19:35
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 16:19:13
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:53:48
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:53:23
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	26 Oct 2020 15:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:10:18
User closed query 'source = 08Oct2020, please verify (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:10:16
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 21:11:15
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	zackery harmon (b) (4) (b) (4)	28 Jan 2021 16:39:43
Query 'source = 08Oct2020, please verify' answered with 'updated' (Site from CRA).	zackery harmon (b) (4) (b) (4)	28 Jan 2021 16:00:12
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	28 Jan 2021 15:59:58
User entered '08 Oct 2020' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	28 Jan 2021 15:59:58
User opened query 'source = 08Oct2020, please verify' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:20:30
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 16:20:17
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:53:48
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:53:30
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:53:48
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:53:32
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User entered empty.	System	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:53:48
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:53:34
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:53:48
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:53:35
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:53:48
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:53:44
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'Not Related (NOT RELATED)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'Not Related (NOT RELATED)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:10:24
User closed query 'as IP dosing was complete should this be Not applicable? Please verify' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 17:55:29
Query 'as IP dosing was complete should this be Not applicable? Please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	25 Nov 2020 13:56:37
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	25 Nov 2020 13:56:33
User opened query 'as IP dosing was complete should this be Not applicable? Please verify' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 20:56:42
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 20:54:08
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'None (NONE)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

US3202191

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'l'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure as appropriate. Otherwise, clarify.' answered with 'Rx only.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 14:28:22
DataPoint Un-verified.	Teresa Deese (b) (4)	18 Feb 2021 17:30:35
User entered '0' reason for change: Data Entry Error	Teresa Deese (b) (4)	18 Feb 2021 17:30:18
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 10:35:20
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:10:30
User closed query 'Per CDM: Please review and verify if this field should be ticked as there is a Concomitant Procedure# 1 recorded that match this AE during this timeframe. Review and update as appropriate, else clarify.' (Site from DM). Query 'Per CDM: Please review and verify if this field should be ticked as there is a Concomitant Procedure# 1 recorded that match this AE during this timeframe. Review and update as appropriate, else clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6) zackery harmon (b) (4)	29 Jan 2021 08:47:21
DataPoint Un-verified.	zackery harmon (b) (4)	28 Jan 2021 16:39:51
User entered '1' reason for change: Data Entry Error	zackery harmon (b) (4)	28 Jan 2021 15:59:58

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:19:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 16:17:20
User opened query 'Per CDM: Please review and verify if this field should be ticked as there is a Concomitant Procedure# 1 recorded that match this AE during this timeframe. Review and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 12:06:38
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	
Query 'please confirm' canceled (Site from CRA).	zackery harmon (b) (4)	28 Jan 2021 16:39:57
	(b) (4)	
Query 'please confirm' canceled (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:19:48
User opened query 'please confirm' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:17:45
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 16:17:34
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Tiffany Jewell (b) (4)	26 Oct 2020 15:39:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[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 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User entered '0'	System	26 Oct 2020 15:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13
User entered 'I'	System	26 Oct 2020 15:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:32:59
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:04:49
Un-reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 18:12:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 18:12:54
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:24
User entered 'USA-US128-2020-mRNA-1273-P301000009'	System	23 Nov 2020 21:44:13
User entered 'New'	(b) (4), (b) (6)	23 Nov 2020 21:44:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:04:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Olecranon bursitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 15:24:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 15:24:31
Data point term sent to Coder	System	25 Nov 2020 14:28:11
DataPoint Un-verified.	Erica Osmundsen (b) (4)	25 Nov 2020 14:27:30
Coding entries removed.	Erica Osmundsen (b) (4)	25 Nov 2020 14:27:30
User entered 'RIGHT OLECRANON BURSITIS (RIGHT ELBOW INFECTION)' reason for change:	Erica Osmundsen (b) (4)	25 Nov 2020 14:27:30
Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 20:51:43
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Wound infection, LLT: Wound infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 09:05:50
Data point term sent to Coder	System	20 Nov 2020 15:29:00
User entered 'RIGHT ELBOW WOUND INFECTION'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '27 Oct 2020'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered empty.	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User entered empty.	System	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:11:53
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:03:56
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	28 Jan 2021 16:42:07
DataPoint Un-verified.	zackery harmon (b) (4) (b) (4)	28 Jan 2021 16:41:29
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	28 Jan 2021 16:41:29
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 18:54:28
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:11:59
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	28 Jan 2021 16:42:01
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	28 Jan 2021 16:42:01
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	28 Jan 2021 16:41:29
DataPoint Un-verified.	zackery harmon (b) (4) (b) (4)	28 Jan 2021 16:41:29
User entered '15 Nov 2020' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	28 Jan 2021 16:41:29
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered empty.	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered empty.	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User entered empty.	System	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'Grade 3/Severe (Grade 3/Severe)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:05:26
DataPoint Un-verified.	Erica Osmundsen (b) (4)	25 Nov 2020 13:37:12
User entered 'No (N)' reason for change: New Information	Erica Osmundsen (b) (4)	25 Nov 2020 13:37:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '0'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:04:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 16:04:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '0'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:04:57
DataPoint Un-verified.	Erica Osmundsen (b) (4)	25 Nov 2020 13:37:12
User entered '0' reason for change: New Information	Erica Osmundsen (b) (4)	25 Nov 2020 13:37:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '1'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:05:01
DataPoint Un-verified.	Erica Osmundsen (b) (4)	25 Nov 2020 13:37:12
User entered empty; reason for change New Information	Erica Osmundsen (b) (4)	25 Nov 2020 13:37:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '26 Oct 2020'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:05:04
DataPoint Un-verified.	Erica Osmundsen (b) (4)	25 Nov 2020 13:37:12
User entered empty; reason for change New Information	Erica Osmundsen (b) (4)	25 Nov 2020 13:37:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '29 Oct 2020'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:05:06
DataPoint Un-verified.	Erica Osmundsen (b) (4)	25 Nov 2020 13:37:12
User entered empty; reason for change Data Entry Error	Erica Osmundsen (b) (4)	25 Nov 2020 13:37:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered empty.	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '0'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '0'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '0'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

US3202191

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered '0'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

US3202191

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'l'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

US3202191

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'l'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

US3202191

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:12:06
DataPoint Un-verified.	zackery harmon (b) (4)	28 Jan 2021 16:42:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) zackery harmon (b) (4)	28 Jan 2021 16:42:01
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

US3202191

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[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 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered empty.	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

US3202191

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:05:12
DataPoint Un-verified.	Erica Osmundsen (b) (4)	25 Nov 2020 13:37:12
User entered 'SUBJECT'S ELBOW LACERATION BECAME INFECTED AND SUBJECT REPORTED HOSPITALIZATION FOR THIS, BUT WHEN RECORDS RECEIVED, THEY REVEALED HE HAD A MINOR PROCEDURE (INCISION AND DRAINAGE) FOR THIS AE AND WAS NOT ADMITTED. HIS HOSPITALIZATION OCCURRED A FEW DAYS LATER FOR SEPARATE ISSUE --ADDING THAT NOW. HE SEEMS TO HAVE BEEN CONFUSED ABOUT THE INDICATION FOR HOSPITALIZATION AND/OR ITS RELATIONSHIP TO THIS AE BASED ON HIS INITIAL REPORT OF EVENT.'	Erica Osmundsen (b) (4)	25 Nov 2020 13:37:12
reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:51:43
User entered 'SUBJECT'S ELBOW LACERATION BECAME INFECTED AND SUBJECT REPORTS SEVERELY INFECTED, HOSPITALIZED 3 DAYS AND SURGERY PERFORMED ON INFECTION SITE. RECORDS REQUESTED.'	Erica Osmundsen (b) (4)	20 Nov 2020 15:29:00

US3202191

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User entered '0'	System	25 Nov 2020 13:37:12
User entered '1'	System	20 Nov 2020 15:29:00

US3202191

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User entered 'I'	System	20 Nov 2020 15:29:00

US3202191

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:19
User entered '0'	System	20 Nov 2020 15:29:00

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:32:59
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:56:44
User entered 'USA-US128-2020-mRNA-1273-P301000009'	(b) (4), (b) (6)	30 Nov 2020 14:47:11

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 19:12:34
User closed query 'per D/C summary diagnosis was "Weakness" please verify' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:12:30
User closed query 'please confirm consult records for ortho (C spine) and Neuro follow up have been requested' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:12:26
Query 'please confirm consult records for ortho (C spine) and Neuro follow up have been requested' answered with 'CONFIRMED--RECORDS REQUESTED' (Site from CRA).	Erica Osmundsen (b) (4)	29 Jan 2021 19:31:46
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Asthenia, LLT: Weakness - version MedDRA\23.0.	Coder Import (b) (4)	28 Jan 2021 16:00:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	28 Jan 2021 16:00:25
Data point term sent to Coder	System	28 Jan 2021 15:58:51
Query 'per D/C summary diagnosis was "Weakness" please verify' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	28 Jan 2021 15:58:47
Coding entries removed.	zackery harmon (b) (4)	28 Jan 2021 15:58:41
User entered 'Weakness' reason for change: Data Entry Error	(b) (4)	
	zackery harmon (b) (4)	28 Jan 2021 15:58:41
User opened query 'please confirm consult records for ortho (C spine) and Neuro follow up have been requested' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:02:48
User opened query 'per D/C summary diagnosis was "Weakness" please verify' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:57:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 16:57:19
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:56:46

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 13:56:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 13:56:08
Data point term sent to Coder	System	25 Nov 2020 13:55:50
User entered 'CEREBRAL VASCULAR ACCIDENT'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:56:47
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:56:49
User entered 'No (N)'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:57:50
User entered 'No (N)'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:57:53
User entered '29 Oct 2020'	Erica Osmundsen (b) (4) 	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:59:26
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:59:28
User entered 'No (N)'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:59:30
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Nov 2020 13:56:13
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	25 Nov 2020 13:56:13
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	25 Nov 2020 13:55:40
User entered '03 Nov 2020'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:59:33
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:59:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erica Osmundsen (b) (4) 	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:00:02
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:00:07
User entered '0'	Erica Osmundsen (b) (4) 	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:00:08
User entered '0'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:00:10
User entered 'I'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:00:13
User entered '30 Oct 2020'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:00:15
User entered '03 Nov 2020'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:00:19
User entered 'No (N)'	Erica Osmundsen (b) (4) 	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:00:26
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:00:30
User entered '0'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:00:32
User entered '0'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:00:34
User entered '0'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:00:37
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4) 	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:00:39
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4) 	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:00:41
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

US3202191

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

None

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:05:34
DataPoint Un-verified.	Erica Osmundsen (b) (4)	05 Mar 2021 20:51:20
User entered '1' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Mar 2021 20:51:20
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Mar 2021 16:24:47
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Feb 2021 17:55:00
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:00:47
User entered '0'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:05:37
User closed query 'Per CDM: Response noted. Please reconcile Indication and Date should match. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 08:02:34
Query 'Per CDM: Response noted. Please reconcile Indication and Date should match. Thank you' answered with 'occupational therapy sessions were the action taken for this specific condition' (Site from DM).	Erica Osmundsen (b) (4)	05 Mar 2021 20:51:50
User entered '0' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Mar 2021 20:51:20
User opened query 'Per CDM: Response noted. Please reconcile Indication and Date should match. Thank you' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 08:34:56
User closed query 'Per CDM: Response to previous query states 'see 15 and 16'? however, CM# 15 is recorded for indication 'IMPROVE SLEEP WHILE HOSPITALIZED' and CM #16 'BACK PAIN OSTEOARTHRITIS'? Please review/update as appropriate ensuring indication/dates match with this record else clarify.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 08:34:56
Query 'Per CDM: Response to previous query states 'see 15 and 16'? however, CM# 15 is recorded for indication 'IMPROVE SLEEP WHILE HOSPITALIZED' and CM #16 'BACK PAIN OSTEOARTHRITIS'? Please review/update as appropriate ensuring indication/dates match with this record else clarify.' answered with 'correction see line 15 not 16, pt was given the medication in the hospital to help him sleep not for his weakness, does the indication need to be updated to weakness to relate it to the AE?' (Site from DM).	zackery harmon (b) (4) (b) (4)	03 Mar 2021 13:45:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Response to previous query states 'see 15 and 16'? however, CM# 15 is recorded for indication ' IMPROVE SLEEP WHILE HOSPITALIZED' and CM #16 ' BACK PAIN OSTEOARTHRITIS'? Please review/update as appropriate ensuring indication/dates match with this record else clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 12:06:48
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 12:06:48
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'see 15 and 16' (Site from DM).	zackery harmon (b) (4)	02 Mar 2021 16:24:54
User entered '1' reason for change: Data Entry Error	zackery harmon (b) (4)	02 Mar 2021 16:24:47
DataPoint Un-verified.	Erica Osmundsen (b) (4)	18 Feb 2021 17:55:00
User entered '0' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	18 Feb 2021 17:55:00
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 10:36:00
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:00:51
User entered '1'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 19:12:43
User closed query 'please verify con procedures performed' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:12:40
User entered '0' reason for change: Data Entry Error	zackery harmon (b) (4)	28 Jan 2021 16:45:00
	(b) (4)	
Query 'please verify con procedures performed' answered with 'Subject had only Diagnostic procedures done, not treatment procedures, only medications' (Site from CRA).	zackery harmon (b) (4)	28 Jan 2021 16:44:42
	(b) (4)	
User opened query 'please verify con procedures performed' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:01:35
User entered '1'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:01:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	25 Nov 2020 13:56:13
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

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Folder: Adverse Events

Form: Adverse Events (3)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:01:47
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that subject had "MULTIPLE FALLS & CT HEAD W/O CONTRAST." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 12:39:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
Query 'Per DM CLR: Narrative indicates that subject had "MULTIPLE FALLS & CT HEAD W/O CONTRAST." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'con proc not needed according to monitor. weakness was Sx & RESULT was falls. therefore weakness was AE not falls' (Site from DM).	Teresa Deese (b) (4)	12 Mar 2021 16:14:01
User opened query 'Per DM CLR: Narrative indicates that subject had "MULTIPLE FALLS & CT HEAD W/O CONTRAST." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:02:38
User closed query 'Per DM CLR: Narrative indicates that the subject had CT without Contrast. However, there is no corresponding Concomitant Procedures record that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 12:07:25
User closed query 'Per DM CLR: Narrative indicates that the subject had multiple events of Fall. However, there is no recorded AE of Fall. Please review and update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 12:07:21
Query 'Per DM CLR: Narrative indicates that the subject had multiple events of Fall. However, there is no recorded AE of Fall. Please review and update to record the corresponding AE as appropriate. Otherwise, clarify.' answered with 'Fall was symptom of the weakness' (Site from DM).	zackery harmon (b) (4)	02 Mar 2021 16:27:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that the subject had CT without Contrast. However, there is no corresponding Concomitant Procedures record that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' answered with 'not a treatment' (Site from DM).	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:27:16
User opened query 'Per DM CLR: Narrative indicates that the subject had CT without Contrast. However, there is no corresponding Concomitant Procedures record that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4)	15 Feb 2021 10:36:28
User opened query 'Per DM CLR: Narrative indicates that the subject had multiple events of Fall. However, there is no recorded AE of Fall. Please review and update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	15 Feb 2021 10:36:18
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	10 Feb 2021 19:12:50
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Feb 2021 12:52:43
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Feb 2021 12:52:41
	(b) (4), (b) (6) (b) (4), (b) (6)	01 Feb 2021 12:52:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'MRSA-POSITIVE CULTURE FROM RIGHT ELBOW WOUND, NO ACUTE FINDINGS ON LABS OR IMAGING' (Site from Safety).	Erica Osmundsen (b) (4)	29 Jan 2021 20:34:40
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'SUBJECT'S DISCHARGE DIAGNOSIS IS LISTED AS "WEAKNESS" SO AE TERM UPDATED PER PI. SUBJECT HAD A CERVICAL SPINE MRI WITH DEGENERATIVE CONDITIONS NOTED, BUT NO ACUTE FINDINGS, ECHOCARDIOGRAM COMPLETED WITH NO ACUTE FINDINGS. CT OF HEAD W/O CONTRAST ON 30/OCT/2020 WITH IMPRESSION LISTED AS SUBACUTE/CHRONIC INFARCTION EVOLVING IN LEFT POSTERIOR L FRONTAL LOB AND CHRONIC INFARCTION IN LEFT CEREBELLAR HEMISPHERE. NEUROLOGY RECORDS REQUESTED, THESE ITEMS WERE ADDED TO MEDICAL HISTORY AS THEY WERE MENTIONED IN RECORDS AS ITEMS PATIENT REPORTED AS POSSIBLE EVENTS HIS NEUROLOGIST HAD NOTED YEARS EARLIER.' (Site from Safety).	Erica Osmundsen (b) (4)	29 Jan 2021 20:33:38
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'no COVID-19 test is mentioned in medical records received to date. Lab results were included in records and no COVID-19 testing was included in these results.' (Site from Safety).	Erica Osmundsen (b) (4)	29 Jan 2021 20:26:22

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 21:58:26
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 21:58:17
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 21:58:09
User entered 'HE REPORTED HOSPITALIZATION ON 19NOV2020 AND STATED IT WAS RELATED TO INFECTED WOUND ON RIGHT ELBOW, WHICH WAS REPORTED AS THE SAE W/IN 24 HOURS OF KNOWLEDGE OF EVENT BY SITE. MEDICAL RECORDS REQUESTED AND RECEIVED BY PI AND STUDY COORDINATOR ON 24NOV2020. RECORDS REVEALED THE HOSPITALIZATION WAS DUE TO WEAKNESS AND BALANCE PROBLEMS RESULTING IN MULTIPLE FALLS IN THE DAYS FOLLOWING OUTPATIENT PROCEDURE. FOR ELBOW WOUND. HE WAS ADMITTED FOR EVAL OF POSSIBLE STROKE. RECORDS REVEALED PRIOR CVA SUSPECTED IN JUNE 2019 AND DIAGNOSIS OF AXONAL NEUROPATHY. CT HEAD W/O CONTRAST IMPRESSION STATES "THERE IS WHAT APPEARS TO BE A SUBACUTE/CHRONIC INFARCTION EVOLVING IN THE POSTERIOR LEFT FRONTAL LOBE. CHRONIC INFARCTION IN THE LEFT CEREBELLAR HEMISPHERE" PER RECORDS. THE D/C DIAGNOSIS LISTED STATES WEAKNESS AND RECOMMENDED F/UP WITH HIS CURRENT NEUROLOGIST.'	Erica Osmundsen (b) (4)	25 Nov 2020 13:55:40

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Folder: Adverse Events

Form: Adverse Events (3)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Nov 2020 13:55:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Nov 2020 13:55:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Nov 2020 13:55:40

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:19
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 14:30:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 14:30:14
Data point term sent to Coder	System	25 Nov 2020 14:29:12
User entered 'URINARY RETENTION'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:21
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:24
User entered 'No (N)'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:27
User entered 'No (N)'	Erica Osmundsen (b) (4) 	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:29
User entered '27 Oct 2020'	Erica Osmundsen (b) (4) 	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:30
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 09:46:58
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'ONGOING' (Site from DM).	Erica Osmundsen (b) (4)	29 Jan 2021 20:45:35
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 18:54:48
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:31:34
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:39
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:37
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:43
User entered 'No (N)'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:48
User entered '0'	Erica Osmundsen (b) (4) 	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:49
User entered '0'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

US3202191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:52
User entered '0'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

US3202191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:54
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:57
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:31:58
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:32:00
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:32:02
User entered '0'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:32:03
User entered '0'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:32:05
User entered '0'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:32:11
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4) 	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:32:13
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4) 	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:32:15
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:32:20
User entered '0'	Erica Osmundsen (b) (4) 	25 Nov 2020 14:28:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:32:22
User entered 'I'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

US3202191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:32:24
User entered '0'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

US3202191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:32:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

US3202191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:32:32
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

US3202191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:32:35
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 14:28:27

US3202191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Nov 2020 14:28:27

US3202191

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:41:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Nov 2020 14:28:27

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:07
User coded data point as SOC: Nervous system disorders, HLG: Peripheral neuropathies, HLT: Mononeuropathies, PT: Cubital tunnel syndrome, LLT: Cubital tunnel syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 21:39:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 21:39:46
Data point term sent to Coder	System	02 Mar 2021 16:35:31
User entered 'L cubital tunnel syndrome'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:09
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:14
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:16
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:18
User entered '02 Dec 2020'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:23
User entered empty.	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User entered empty.	System	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 12:40:22
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Un-verified.	(b) (4)	
	Teresa Deese (b) (4)	12 Mar 2021 16:14:54
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	12 Mar 2021 16:14:54
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	12 Mar 2021 16:14:22
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:03:04
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:06:24
User entered 'Yes (Y)'	zackery harmon (b) (4)	02 Mar 2021 16:34:45
	(b) (4)	

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Un-verified.	(b) (4) Teresa Deese (b) (4)	12 Mar 2021 16:14:54
User entered '2 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	12 Mar 2021 16:14:54
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:06:26
User entered empty.	zackery harmon (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:29
User entered empty.	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User entered empty.	System	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:33
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:32
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:36
User entered '0'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:38
User entered '0'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:39
User entered '0'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:43
User entered empty.	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:56
User entered empty.	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:58
User entered empty.	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:06:59
User entered empty.	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:07:01
User entered '0'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:07:03
User entered '0'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:07:05
User entered '0'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:07:07
User entered 'Not Related (NOT RELATED)'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:07:09
User entered 'Not Related (NOT RELATED)'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:07:10
User entered 'Not Applicable (NOT APPLICABLE)'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	12 Mar 2021 16:15:02
DataPoint Un-verified.	Teresa Deese (b) (4)	12 Mar 2021 16:15:02
User entered '0' reason for change: Data Entry Error	Teresa Deese (b) (4)	12 Mar 2021 16:15:02
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	12 Mar 2021 16:14:54
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:07:14
User entered '1'	zackery harmon (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:11
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:39:54
Signature has been broken.	zackery harmon (b) (4)	23 Mar 2021 15:55:41
User entered '0' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	zackery harmon (b) (4)	23 Mar 2021 15:55:28
User signature succeeded.	(b) (4)	
DataPoint Un-verified.	zackery harmon (b) (4)	23 Mar 2021 15:55:28
User entered '1' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 08:41:42
User entered '0'	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
	Teresa Deese (b) (4)	12 Mar 2021 16:14:54
	Teresa Deese (b) (4)	12 Mar 2021 16:14:54
	(b) (4), (b) (6)	10 Mar 2021 20:07:15
	zackery harmon (b) (4)	02 Mar 2021 16:34:45
	(b) (4)	

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Un-verified.	(b) (4) Teresa Deese (b) (4)	12 Mar 2021 16:14:54
User entered '1' reason for change: Data Entry Error	(b) (4) Teresa Deese (b) (4)	12 Mar 2021 16:14:54
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:07:17
User entered '0'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Un-verified.	(b) (4) Teresa Deese (b) (4)	12 Mar 2021 16:14:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Teresa Deese (b) (4)	12 Mar 2021 16:14:54
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:07:18
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[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 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:07:20
User entered empty.	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:07:22
User entered empty.	zackery harmon (b) (4) (b) (4)	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User entered '0'	System	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31
User entered 'I'	System	02 Mar 2021 16:34:45

US3202191

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:31

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Wound dehiscence, LLT: Wound dehiscence - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 02:48:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 02:48:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:14:47
Data point term sent to Coder	System	12 Mar 2021 16:21:35
User entered 'dehiscence of left cubital tunnel sutures'	Teresa Deese (b) (4) (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered '9 Mar 2021'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:11
User closed query 'Per DM CLR: Please review and please note, there is a recorded ConMed that match this AE. However, Concomitant Medications is not selected as Other Action Taken. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 09:50:01
Query 'Per DM CLR: Please review and please note, there is a recorded ConMed that match this AE. However, Concomitant Medications is not selected as Other Action Taken. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	23 Mar 2021 15:56:24
Signature has been broken.	zackery harmon (b) (4) (b) (4)	23 Mar 2021 15:56:11
User entered '1' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	23 Mar 2021 15:56:11
User opened query 'Per DM CLR: Please review and please note, there is a recorded ConMed that match this AE. However, Concomitant Medications is not selected as Other Action Taken. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 08:41:24
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:14:47
User entered '0'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered 'I'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:14:47
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:41:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 16:21:00

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User closed query 'Per CDM: Please specify location of JOINT ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:47:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 13:34:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 13:34:26
Query 'Per CDM: Please specify location of JOINT ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' answered with 'SOLICITED AR UPDATED TERM PER CCGs, NO MED' (Site from DM).	Erica Osmundsen (b) (4)	21 Apr 2021 13:31:48
Data point term sent to Coder	System	21 Apr 2021 13:31:42
Coding entries removed.	Erica Osmundsen (b) (4)	21 Apr 2021 13:31:03
User entered 'ARTHRALGIA (JOINT ACHES)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	21 Apr 2021 13:31:03
User opened query 'Per CDM: Please specify location of JOINT ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 08:48:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 14:22:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 14:22:18
Data point term sent to Coder	System	20 Apr 2021 14:21:23

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Joint Aches'	zackery harmon (b) (4) (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48
	(b) (4)	

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Apr 2021 14:21:17
User entered '21:00' reason for change: Data Entry Error	System	20 Apr 2021 14:21:17
User opened query 'Data is required. Please provide.' (Site from System).	zackery harmon (b) (4)	20 Apr 2021 14:20:48
User entered empty.	(b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User entered '14 Aug 2020 21:00'	System	20 Apr 2021 14:21:17
User entered empty.	System	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '12 Sep 2020'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	20 Apr 2021 14:21:17
User entered '07:00' reason for change: Data Entry Error	System	20 Apr 2021 14:21:17
User opened query 'Data is required. Please provide.' (Site from System).	zackery harmon (b) (4)	20 Apr 2021 14:20:48
User entered empty.	(b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User entered '12 Sep 2020 07:00'	System	20 Apr 2021 14:21:17
User entered empty.	System	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48
	(b) (4)	

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Related (RELATED)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Not Related (NOT RELATED)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'None (NONE)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'I'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:41:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[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 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User entered '0'	System	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40
User entered '0'	System	20 Apr 2021 14:20:48

US3202191

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:40

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Folder: Adverse Events

Form: Adverse Events (8)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User closed query 'Per CDM: Please specify location of MUSCLE ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:48:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 13:36:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 13:36:54
Query 'Per CDM: Please specify location of MUSCLE ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' answered with 'SOLICITED AR UPDATED TERM PER CCGs, NO MED' (Site from DM).	Erica Osmundsen (b) (4)	21 Apr 2021 13:32:56
Data point term sent to Coder	System	21 Apr 2021 13:32:44
Coding entries removed.	Erica Osmundsen (b) (4)	21 Apr 2021 13:32:19
User entered 'MYALGIA (MUSCLE ACHES)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	21 Apr 2021 13:32:19
User opened query 'Per CDM: Please specify location of MUSCLE ACHES and ensure that there is a corresponding CM record that reconciles with this provided event if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 08:49:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 14:23:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 14:23:07
Data point term sent to Coder	System	20 Apr 2021 14:22:23
User entered 'Muscle aches'	zackery harmon (b) (4) (b) (4)	20 Apr 2021 14:22:08

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EAB) (1725)

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '14 Aug 2020'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '21:00'	(b) (4) zackery harmon (b) (4) (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User entered '14 Aug 2020 21:00'	System	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '12 Sep 2020'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '07:00'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User entered '12 Sep 2020 07:00'	System	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Related (RELATED)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

US3202191

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Not Related (NOT RELATED)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

US3202191

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'None (NONE)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:41:09

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'I'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Generated On: 09 Jun 2021 15:41:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

US3202191

Folder: Adverse Events

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Generated On: 09 Jun 2021 15:41:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:41:09

[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 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User entered '0'	System	20 Apr 2021 14:22:08

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Folder: Adverse Events

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48
User entered '0'	System	20 Apr 2021 14:22:08

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:48

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
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)	20 Apr 2021 14:24:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 14:24:06
Data point term sent to Coder	System	20 Apr 2021 14:23:24
User entered 'Fatigue'	zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '15 Aug 2020'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	20 Apr 2021 14:23:11
User entered '08:00' reason for change: Data Entry Error	zackery harmon (b) (4)	20 Apr 2021 14:23:11
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Apr 2021 14:22:54
User entered empty.	zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User entered '15 Aug 2020 08:00'	System	20 Apr 2021 14:23:11
User entered empty.	System	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '12 Sep 2020'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	20 Apr 2021 14:23:11
User entered '07:00' reason for change: Data Entry Error	zackery harmon (b) (4)	20 Apr 2021 14:23:11
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Apr 2021 14:22:54
User entered empty.	zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User entered '12 Sep 2020 07:00'	System	20 Apr 2021 14:23:11
User entered empty.	System	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Related (RELATED)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Not Related (NOT RELATED)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'None (NONE)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'I'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered '0'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[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 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:23
User entered empty.	(b) (4) zackery harmon (b) (4)	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User entered '0'	System	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49
User entered '0'	System	20 Apr 2021 14:22:54

US3202191

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:41:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:00:49

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:41:09

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User closed query 'per hospital record subject received the following meds while in hospital- please review, reconcile, and update: KCL po, Biscodyl per rectum, Essential fatty Acids, Kphos, Vitamin B12, Cholecalciferol, Aspirin, Docusate, Pantoprazole, Zofran, Normal Saline' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:27:58
Query 'per hospital record subject received the following meds while in hospital- please review, reconcile, and update: KCL po, Biscodyl per rectum, Essential fatty Acids, Kphos, Vitamin B12, Cholecalciferol, Aspirin, Docusate, Pantoprazole, Zofran, Normal Saline' answered with 'all medications reviewed with subject and some listed in records were old entries that subject was not taking any longer' (Site from CRA).	Erica Osmundsen (b) (4)	05 Mar 2021 20:53:02
User opened query 'per hospital record subject received the following meds while in hospital- please review, reconcile, and update: KCL po, Biscodyl per rectum, Essential fatty Acids, Kphos, Vitamin B12, Cholecalciferol, Aspirin, Docusate, Pantoprazole, Zofran, Normal Saline' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:35:27
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:14:10
User closed query 'please review discharge summary and add all medications taken during hospitalization and discharge meds' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:14:08
User closed query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Any use of prescription pain reliever or prevents daily 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).	(b) (4), (b) (6)	01 Feb 2021 11:05:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:41:09

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Any use of prescription pain reliever or prevents daily 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 'PER PHONE CALL NOTES, SUBJECT WAS RESPONDING "YES" TO MEDICATIONS BASED ON HIS DAILY MEDICATIONS TAKEN PRIOR TO STUDY. RE-EDUCATED' (Site from DM).	Erica Osmundsen (b) (4)	29 Jan 2021 20:51:14
Query 'please review discharge summary and add all medications taken during hospitalization and discharge meds' answered with 'MEDICATIONS RECONCILED WITH SUBJECT AND UPDATED AS NEEDED' (Site from CRA).	Erica Osmundsen (b) (4)	29 Jan 2021 20:47:17
User opened query 'Per DM CLR: Per Diary Dose 1 Day 3, Headache (General) = Any use of prescription pain reliever or prevents daily 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).	(b) (4), (b) (6)	14 Jan 2021 07:54:08
User opened query 'please review discharge summary and add all medications taken during hospitalization and discharge meds' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:28:00
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:45:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Sep 2020 22:48:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 22:48:44
Data point term sent to Coder User entered 'AMLODIPINE'	System Erica Osmundsen (b) (4) (b) (4) (b) (4)	17 Sep 2020 22:47:13 17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'HYPERTENSION'	Erica Osmundsen (b) (4)	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '5'	Erica Osmundsen (b) (4)	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '27 Jun 2018'	Erica Osmundsen (b) (4)	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 22:46:23

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
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)	17 Sep 2020 22:49:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 22:49:45
Data point term sent to Coder	System	17 Sep 2020 22:48:13
User entered 'ATORVASTATIN'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'HIGH CHOLESTEROL'	Erica Osmundsen (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '40'	Erica Osmundsen (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '11 Feb 2016'	Erica Osmundsen (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 22:47:20

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Sep 2020 22:49:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 22:49:45
Data point term sent to Coder	System	17 Sep 2020 22:49:16
User entered 'ELIQUIS'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'ATRIAL FIBRILLATION'	Erica Osmundsen (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '5'	Erica Osmundsen (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'twice daily (BID)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '15 Sep 2019'	Erica Osmundsen (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 22:48:16

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Sep 2020 22:50:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 22:50:37
Data point term sent to Coder	System	17 Sep 2020 22:50:17
User entered 'LISINOPRIL'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'HYPERTENSION'	Erica Osmundsen (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '12.5'	Erica Osmundsen (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '18 Jun 2018'	Erica Osmundsen (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 22:49:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: SOTALOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Sep 2020 22:51:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 22:51:39
Data point term sent to Coder	System	17 Sep 2020 22:51:18
User entered 'SOTALOL'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'ATRIAL FIBRILLATION'	Erica Osmundsen (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '80'	Erica Osmundsen (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'twice daily (BID)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '15 Sep 2019'	Erica Osmundsen (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 22:50:58

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: ANORO ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 22:53:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 22:53:49
Data point term sent to Coder	System	17 Sep 2020 22:53:19
User entered 'ANORA ELLIPTA'	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE'	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '62.5/25'	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'ug (ug)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '11 Feb 2020'	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 22:52:24

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Sep 2020 22:55:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 22:55:39
Data point term sent to Coder User entered 'CELECOXIB'	System Erica Osmundsen (b) (4)	17 Sep 2020 22:54:20 17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'OSTEOARTHRITIS'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '200'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'mg (mg)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'twice daily (BID)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Oral (ORAL)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'UN UNK 2004'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User closed query 'per D/C summary this was to stop upon D/C 03Nov20. Please verify' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:27:40
Query 'per D/C summary this was to stop upon D/C 03Nov20. Please verify' answered with 'updated' (Site from CRA).	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:11:47
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:02:42
User opened query 'per D/C summary this was to stop upon D/C 03Nov20. Please verify' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:08:35
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	zackery harmon (b) (4)	29 Jan 2021 17:02:42
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User entered '2'	System	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User entered '1'	System	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:19
User entered '804 (804)'	System	17 Sep 2020 22:53:30

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: DUTASTERIDE;TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: JALYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 22:56:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 22:56:40
Data point term sent to Coder	System	17 Sep 2020 22:55:23
User entered 'JALYN'	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'BENIGN PROSTATIC HYPERPLASIA'	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '0.4/0.5'	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '21 Nov 2012'	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 22:54:40

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE, PRODUCTSYNONYM: REGLAN [METOCLOPRAMIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Sep 2020 05:31:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 05:31:44
Data point term sent to Coder	System	17 Sep 2020 22:56:25
User entered 'REGLAN'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Erica Osmundsen (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '10'	Erica Osmundsen (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'four times daily (QID)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'UN UNK 1999'	Erica Osmundsen (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:32
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 22:55:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
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: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Sep 2020 22:57:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 22:57:43
Data point term sent to Coder	System	17 Sep 2020 22:56:24
User entered 'NEXIUM'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'GERD'	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '40'	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'UN UNK 2004'	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 22:56:21

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 06:09:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 06:09:49
Data point term sent to Coder	System	17 Sep 2020 22:58:27
User entered 'HYDROCODONE/ACETAMINOPHEN 10/325'	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'CHRONIC BACK PAIN'	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '1'	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'tablet (TABLET)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '06 Apr 2018'	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '0'	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Erica Osmundsen (b) (4)	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 22:57:51

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 16:58:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 16:58:23
Data point term sent to Coder	System	26 Oct 2020 15:42:44
User entered 'Sulfamethoxazole Trimethoprim'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:02
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:05
User entered 'Laceration of right elbow'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:10
User entered '800/160'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:13
User entered 'mg (mg)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:15
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:17
User entered 'twice daily (BID)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:26
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:27
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:15:47
DataPoint Un-verified.	zackery harmon (b) (4)	29 Jan 2021 17:04:39
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4) zackery harmon (b) (4)	29 Jan 2021 17:04:39
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:29:32
User entered '8 Oct 2020'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:29:34
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:15:49
User closed query 'per source Docycycline started 29Oct2020 as replacement. Please verify and provide end date' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:15:40
Query 'per source Docycycline started 29Oct2020 as replacement. Please verify and provide end date' answered with 'updated' (Site from CRA).	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:04:52
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:04:39
User opened query 'per source Docycycline started 29Oct2020 as replacement. Please verify and provide end date' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:30:10
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:15:53
User entered '29 Oct 2020' reason for change: Data Entry Error	zackery harmon (b) (4)	29 Jan 2021 17:04:39
User entered empty.	(b) (4) Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:30:13
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User entered '2'	System	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User entered '1'	System	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:38
User entered '804 (804)'	System	26 Oct 2020 15:42:18

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 14:34:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 14:34:19
Data point term sent to Coder	System	25 Nov 2020 14:30:13
Coding entries removed.	Erica Osmundsen (b) (4)	25 Nov 2020 14:30:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:57:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 09:05:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 09:05:21
Data point term sent to Coder	System	20 Nov 2020 15:34:09
User entered 'DOXYCYCLINE'	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:57:34
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:16:07
DataPoint Un-verified.	Erica Osmundsen (b) (4)	25 Nov 2020 14:30:11
User entered 'RIGHT OLECRANON BURSITIS' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	25 Nov 2020 14:30:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:57:36
User entered 'RIGHT ELBOW WOUND INFECTION'	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:16:12
DataPoint Un-verified.	Erica Osmundsen (b) (4)	25 Nov 2020 14:30:11
User entered '100' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	25 Nov 2020 14:30:11
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:57:39
User entered '120'	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:57:41
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:57:43
User entered empty.	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:57:44
User entered 'twice daily (BID)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:57:46
User entered empty.	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:57:48
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:57:51
User entered empty.	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:16:18
DataPoint Un-verified.	zackery harmon (b) (4)	29 Jan 2021 17:06:35
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4) zackery harmon (b) (4)	29 Jan 2021 17:06:35
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:57:53
User entered '29 Oct 2020'	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:57:55
User entered '0'	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:16:25
User closed query 'per D/C summary 18 pills were written on 03Nov2020 which would be 9 days after d/c for last med. Please verify' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:16:23
Query 'per D/C summary 18 pills were written on 03Nov2020 which would be 9 days after d/c for last med. Please verify' answered with 'updated' (Site from CRA).	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:07:07
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:06:00
User opened query 'per D/C summary 18 pills were written on 03Nov2020 which would be 9 days after d/c for last med. Please verify' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 17:13:16
DataPoint Un-verified.	(b) (4), (b) (6)	07 Jan 2021 17:10:03
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:57:57
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:58:48
User closed query 'source = Dec date which does not reconcile. please verify and update' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 17:28:21
Query 'source = Dec date which does not reconcile. please verify and update' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	02 Mar 2021 18:34:10
User entered '08 Dec 2020' reason for change: Data Entry Error	Teresa Deese (b) (4)	02 Mar 2021 18:34:04
User opened query 'source = Dec date which does not reconcile. please verify and update' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:18:41
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	29 Jan 2021 17:06:35
User entered '07 Nov 2020' reason for change: Data Entry Error	zackery harmon (b) (4)	29 Jan 2021 17:06:35
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	29 Jan 2021 17:06:00
DataPoint Un-verified.	zackery harmon (b) (4)	29 Jan 2021 17:06:00
User entered '07 Nov 2021' reason for change: Data Entry Error	zackery harmon (b) (4)	29 Jan 2021 17:06:00
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 20:57:58
User entered empty.	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 20:58:02
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User entered '2'	System	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User entered '1'	System	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:44
User entered '804 (804)'	System	20 Nov 2020 15:33:47

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 12:59:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 12:59:55
Data point term sent to Coder	System	05 Mar 2021 20:54:47
Coding entries removed.	Erica Osmundsen (b) (4)	05 Mar 2021 20:53:53
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:21:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 14:38:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 14:38:09
Data point term sent to Coder	System	25 Nov 2020 14:36:18
User entered 'DIPHENHYDRAMINE HYDROCHLORIDE'	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:01:20
DataPoint Un-verified.	Erica Osmundsen (b) (4)	05 Mar 2021 20:53:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Mar 2021 20:53:53
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:20:54
DataPoint Un-verified.	zackery harmon (b) (4)	29 Jan 2021 17:10:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) zackery harmon (b) (4)	29 Jan 2021 17:10:57
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:21:03
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:01:22
User closed query 'Per CDM: Response noted, however verify that this is not expected indication for this medication, Please verify the source and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 08:43:24
Query 'Per CDM: Response noted, however verify that this is not expected indication for this medication, Please verify the source and update accordingly, else clarify. ' answered with 'updated' (Site from DM).	Erica Osmundsen (b) (4)	05 Mar 2021 20:54:01
DataPoint Un-verified.	Erica Osmundsen (b) (4)	05 Mar 2021 20:53:53
User entered 'prevention of sleeplessness' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Mar 2021 20:53:53
User opened query 'Per CDM: Response noted, however verify that this is not expected indication for this medication, Please verify the source and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 15:06:50
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 15:06:50
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'this was ordered in hospital only if subject needed it for sleep. no records that show it was taken. how do want to word the indication?' (Site from DM).	Teresa Deese (b) (4)	02 Mar 2021 18:44:48

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 22:24:46
User closed query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 11:05:51
Query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' answered with 'updated' (Site from DM).	zackery harmon (b) (4)	29 Jan 2021 17:11:02
User opened query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 23:43:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:21:06
User entered 'IMPROVE SLEEP WHILE HOSPITALIZED'	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:21:08
User entered '25'	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:21:10
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:21:11
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:21:13
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:21:15
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:21:18
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:21:19
User entered empty.	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:21:21
User entered '31 Oct 2020'	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:21:23
User entered '0'	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:21:25
User entered 'No (N)'	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:21:29
User entered '02 Nov 2020'	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:21:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User entered empty.	System	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User entered empty.	System	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:55:51
User entered empty.	System	25 Nov 2020 14:36:06

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User closed query 'Per DM CLR: Con Med LIDOCANE PATCH 5% was added/changed on 03 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 12:01:34
Query 'Per DM CLR: Con Med LIDOCANE PATCH 5% was added/changed on 03 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'no worsening per subject' (Site from DM).	Teresa Deese (b) (4)	02 Mar 2021 18:36:59
User opened query 'Per DM CLR: Con Med LIDOCANE PATCH 5% was added/changed on 03 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 22:24:57
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 19:21:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 09:55:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 09:55:46
Data point term sent to Coder	System	29 Jan 2021 17:13:17
User entered 'Lidocane patch 5%'	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:21
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:28
User entered 'back pain osteoarthritis'	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:26
User entered 'I'	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:32
User entered 'Other (OTHER)'	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:35
User entered 'patch'	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:38
User entered 'once daily (QD)'	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:21:57
User entered empty.	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:00
User entered 'Transdermal (TRANSDERMAL)'	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:04
User entered empty.	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:18
User entered '03 Nov 2020'	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:21
User entered '0'	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:23
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:25
User entered empty.	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:22:28
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jan 2021 17:12:42

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Mar 2021 06:58:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 06:58:54
Data point term sent to Coder	System	12 Mar 2021 16:22:35
User entered 'doxycycline'	Teresa Deese (b) (4) (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'dehiscence of left cubital tunnel release sutures'	Teresa Deese (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '100'	Teresa Deese (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'mg (mg)'	Teresa Deese (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'twice daily (BID)'	Teresa Deese (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '10 Mar 2021'	Teresa Deese (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered '0'	Teresa Deese (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'Yes (Y)'	Teresa Deese (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered empty.	Teresa Deese (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
User entered 'No (N)'	Teresa Deese (b) (4)	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:41:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Mar 2021 16:22:13

US3202191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:41:09

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:11:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	20 Nov 2020 15:34:28
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	24 Sep 2020 22:02:55

US3202191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:41:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:15:33
User entered '27 Oct 2020'	Erica Osmundsen (b) (4)	20 Nov 2020 15:35:04

US3202191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:41:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 19:11:06
User closed query 'per source, "Incision and Drainage of Olecranon Bursa". Please verify' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 19:11:04
Query 'per source, "Incision and Drainage of Olecranon Bursa". Please verify' answered with 'fixed' (Site from CRA).	zackery harmon (b) (4)	28 Jan 2021 16:39:30
	(b) (4)	
User entered 'Incision and Drainage of Olecranon Bursa' reason for change: Data Entry Error	zackery harmon (b) (4)	28 Jan 2021 16:39:26
	(b) (4)	
User opened query 'per source, "Incision and Drainage of Olecranon Bursa". Please verify' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 16:15:31
User entered 'WOUND DEBRIDEMENT RIGHT ELBOW'	Erica Osmundsen (b) (4)	20 Nov 2020 15:35:04

US3202191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:15:36
User entered 'Adverse Event (AE)'	Erica Osmundsen (b) (4) 	20 Nov 2020 15:35:04

US3202191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:41:09

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 16:15:39
User entered empty.	Erica Osmundsen (b) (4)	20 Nov 2020 15:35:04

US3202191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:41:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:56:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '2 Feb 2021'	(b) (4) Teresa Deese (b) (4)	12 Mar 2021 16:16:02

US3202191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:41:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:56:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'left cubital tunnel release'	(b) (4) Teresa Deese (b) (4)	12 Mar 2021 16:16:02

US3202191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:56:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Adverse Event (AE)'	(b) (4) Teresa Deese (b) (4)	12 Mar 2021 16:16:02

US3202191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:41:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:56:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Teresa Deese (b) (4)	12 Mar 2021 16:16:02

US3202191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:41:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:56:40
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered '9 Mar 2021'	(b) (4) Teresa Deese (b) (4)	12 Mar 2021 16:24:32

US3202191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:41:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:56:40
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'resuture of left cubital tunnel release surgery'	(b) (4) Teresa Deese (b) (4)	12 Mar 2021 16:24:32

US3202191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:41:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:56:40
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered 'Adverse Event (AE)'	(b) (4) Teresa Deese (b) (4)	12 Mar 2021 16:24:32

US3202191

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:41:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:56:40
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
User entered empty.	(b) (4) Teresa Deese (b) (4)	12 Mar 2021 16:24:32

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered	System	23 Nov 2020 21:44:13
'USA-US128-2020-MRNA-1273-P301000009'		

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Mark'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'McKenzie'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '6035 SHALLOWFORD ROAD SUITE 109'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'TN'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '37421'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'US'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Mar 2021 16:18:12
User entered '8'	System	08 Mar 2021 14:36:32
User entered '7'	System	03 Mar 2021 19:02:49
User entered '6'	System	18 Feb 2021 20:31:40
User entered '5'	System	01 Feb 2021 12:53:20
User entered '4'	System	29 Jan 2021 18:14:51
User entered '3'	System	30 Nov 2020 18:13:36
User entered '2'	System	30 Nov 2020 14:48:54
User entered '1'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered	System	23 Nov 2020 21:44:13
'USA-US128-2020-MRNA-1273-P301000009'		

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Mark'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'McKenzie'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '6035 SHALLOWFORD ROAD SUITE 109'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'TN'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '37421'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'US'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Mar 2021 16:18:12
User entered '8'	System	08 Mar 2021 14:36:32
User entered '7'	System	03 Mar 2021 19:02:49
User entered '6'	System	18 Feb 2021 20:31:40
User entered '5'	System	01 Feb 2021 12:53:20
User entered '4'	System	29 Jan 2021 18:14:51
User entered '3'	System	30 Nov 2020 18:13:36
User entered '2'	System	30 Nov 2020 14:48:54
User entered '1'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:41:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:30:55
User entered '23/Nov/2020 16:44'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:41:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered	System	23 Nov 2020 21:44:13
'USA-US128-2020-MRNA-1273-P301000009'		

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Mark'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'McKenzie'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '6035 SHALLOWFORD ROAD SUITE 109'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'TN'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '37421'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'US'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Mar 2021 16:18:12
User entered '8'	System	08 Mar 2021 14:36:32
User entered '7'	System	03 Mar 2021 19:02:49
User entered '6'	System	18 Feb 2021 20:31:40
User entered '5'	System	01 Feb 2021 12:53:20
User entered '4'	System	29 Jan 2021 18:14:51
User entered '3'	System	30 Nov 2020 18:13:36
User entered '2'	System	30 Nov 2020 14:48:54
User entered '1'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:41:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:30:55
User entered '30/Nov/2020 09:48'	System	30 Nov 2020 14:48:54

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:41:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 18:13:20
User entered 'I'	(b) (4), (b) (6)	30 Nov 2020 14:48:54

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered	System	23 Nov 2020 21:44:13
'USA-US128-2020-MRNA-1273-P301000009'		

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Mark'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'McKenzie'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '6035 SHALLOWFORD ROAD SUITE 109'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'TN'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '37421'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'US'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Mar 2021 16:18:12
User entered '8'	System	08 Mar 2021 14:36:32
User entered '7'	System	03 Mar 2021 19:02:49
User entered '6'	System	18 Feb 2021 20:31:40
User entered '5'	System	01 Feb 2021 12:53:20
User entered '4'	System	29 Jan 2021 18:14:51
User entered '3'	System	30 Nov 2020 18:13:36
User entered '2'	System	30 Nov 2020 14:48:54
User entered '1'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:41:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 17:30:55
User entered '30/Nov/2020 13:13'	System	30 Nov 2020 18:13:36

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:41:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:16:15
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
User entered 'I'	(b) (4), (b) (6)	30 Nov 2020 18:13:36

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered	System	23 Nov 2020 21:44:13
'USA-US128-2020-MRNA-1273-P301000009'		

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Mark'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'McKenzie'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '6035 SHALLOWFORD ROAD SUITE 109'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'TN'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '37421'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'US'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Mar 2021 16:18:12
User entered '8'	System	08 Mar 2021 14:36:32
User entered '7'	System	03 Mar 2021 19:02:49
User entered '6'	System	18 Feb 2021 20:31:40
User entered '5'	System	01 Feb 2021 12:53:20
User entered '4'	System	29 Jan 2021 18:14:51
User entered '3'	System	30 Nov 2020 18:13:36
User entered '2'	System	30 Nov 2020 14:48:54
User entered '1'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:41:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:08:10
User entered '29/Jan/2021 13:14'	System	29 Jan 2021 18:14:51

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:41:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:08:10
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 18:16:15
User entered 'I'	(b) (4), (b) (6)	29 Jan 2021 18:14:51

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered	System	23 Nov 2020 21:44:13
'USA-US128-2020-MRNA-1273-P301000009'		

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Mark'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'McKenzie'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '6035 SHALLOWFORD ROAD SUITE 109'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'TN'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '37421'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'US'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Mar 2021 16:18:12
User entered '8'	System	08 Mar 2021 14:36:32
User entered '7'	System	03 Mar 2021 19:02:49
User entered '6'	System	18 Feb 2021 20:31:40
User entered '5'	System	01 Feb 2021 12:53:20
User entered '4'	System	29 Jan 2021 18:14:51
User entered '3'	System	30 Nov 2020 18:13:36
User entered '2'	System	30 Nov 2020 14:48:54
User entered '1'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:41:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:08:10
User entered '01/Feb/2021 12:53'	System	01 Feb 2021 12:53:20

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:41:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:08:10
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:31:25
User entered 'I'	(b) (4), (b) (6)	01 Feb 2021 12:53:20

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered	System	23 Nov 2020 21:44:13
'USA-US128-2020-MRNA-1273-P301000009'		

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Mark'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'McKenzie'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '6035 SHALLOWFORD ROAD SUITE 109'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'TN'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '37421'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'US'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Mar 2021 16:18:12
User entered '8'	System	08 Mar 2021 14:36:32
User entered '7'	System	03 Mar 2021 19:02:49
User entered '6'	System	18 Feb 2021 20:31:40
User entered '5'	System	01 Feb 2021 12:53:20
User entered '4'	System	29 Jan 2021 18:14:51
User entered '3'	System	30 Nov 2020 18:13:36
User entered '2'	System	30 Nov 2020 14:48:54
User entered '1'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:41:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:08:10
User entered '18/Feb/2021 15:31'	System	18 Feb 2021 20:31:40

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:41:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:08:10
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 19:02:28
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 20:31:40

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered	System	23 Nov 2020 21:44:13
'USA-US128-2020-MRNA-1273-P301000009'		

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Mark'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'McKenzie'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '6035 SHALLOWFORD ROAD SUITE 109'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'TN'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '37421'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'US'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Mar 2021 16:18:12
User entered '8'	System	08 Mar 2021 14:36:32
User entered '7'	System	03 Mar 2021 19:02:49
User entered '6'	System	18 Feb 2021 20:31:40
User entered '5'	System	01 Feb 2021 12:53:20
User entered '4'	System	29 Jan 2021 18:14:51
User entered '3'	System	30 Nov 2020 18:13:36
User entered '2'	System	30 Nov 2020 14:48:54
User entered '1'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:41:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:08:10
User entered '03/Mar/2021 13:02'	System	03 Mar 2021 19:02:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:41:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:10
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:33:41
User entered 'I'	(b) (4), (b) (6)	03 Mar 2021 19:02:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered	System	23 Nov 2020 21:44:13
'USA-US128-2020-MRNA-1273-P301000009'		

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Mark'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'McKenzie'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '6035 SHALLOWFORD ROAD SUITE 109'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'TN'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '37421'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'US'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Mar 2021 16:18:12
User entered '8'	System	08 Mar 2021 14:36:32
User entered '7'	System	03 Mar 2021 19:02:49
User entered '6'	System	18 Feb 2021 20:31:40
User entered '5'	System	01 Feb 2021 12:53:20
User entered '4'	System	29 Jan 2021 18:14:51
User entered '3'	System	30 Nov 2020 18:13:36
User entered '2'	System	30 Nov 2020 14:48:54
User entered '1'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:41:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:08:10
User entered '08/Mar/2021 09:36'	System	08 Mar 2021 14:36:32

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:41:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:10
Reviewed for Safety.	(b) (4), (b) (6)	08 Mar 2021 14:36:47
User entered 'I'	(b) (4), (b) (6)	08 Mar 2021 14:36:32

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered	System	23 Nov 2020 21:44:13
'USA-US128-2020-MRNA-1273-P301000009'		

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'Yes (Y)'	System	30 Nov 2020 14:47:11
Un-reviewed for Safety.	System	25 Nov 2020 13:37:12
User entered 'No (N)'	System	25 Nov 2020 13:37:12
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Yes (Y)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'No (N)'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'Mark'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 21:44:36
User entered 'McKenzie'	System	23 Nov 2020 21:44:13

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '6035 SHALLOWFORD ROAD SUITE 109'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'CHATTANOOGA'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered 'TN'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered empty.	System	30 Nov 2020 14:47:11
User entered '37421'	Erica Osmundsen (b) (4)	25 Nov 2020 13:57:30

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:54
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 12:52:51
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 17:30:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:48:39
User entered 'US'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 15:41:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Mar 2021 16:18:12
User entered '8'	System	08 Mar 2021 14:36:32
User entered '7'	System	03 Mar 2021 19:02:49
User entered '6'	System	18 Feb 2021 20:31:40
User entered '5'	System	01 Feb 2021 12:53:20
User entered '4'	System	29 Jan 2021 18:14:51
User entered '3'	System	30 Nov 2020 18:13:36
User entered '2'	System	30 Nov 2020 14:48:54
User entered '1'	System	23 Nov 2020 21:44:49

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:41:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:08:10
User entered '08/Mar/2021 11:18'	System	08 Mar 2021 16:18:12

US3202191

Folder: SAE USA-US128-2020-MRNA-1273-P301000009

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:41:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:35:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 20:08:10
User entered 'I'	(b) (4), (b) (6)	08 Mar 2021 16:18:12