

US3022031 (Prod: Meridian Clinical Research-Savannah)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:49:51

All time stamps listed in this document are displayed in GMT

US3022031

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

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Participant ID

US3022031

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

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US3022031

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

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Was this visit performed? Yes   
No

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Visit date (dd MMM yyyy) 27 JUL 2020

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

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Folder OID SCRN

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US3022031

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	66
Age Units	YEARS
Age (Derived)	66
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

US3022031

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Date of Informed Consent (*dd MMM yyyy*) 27 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously? Yes   
No

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3022031

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

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Did the participant meet all eligibility criteria?

Yes

No

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US3022031

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

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Were any significant conditions reported?

Yes

No

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US3022031

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

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

US3022031

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	RIGHT LEG SURGERY
Start date (dd MMM yyyy)	UN UNK 1976
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1976
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1976
Start Year (derived)	1976
Stop Month and Year (derived)	JAN 1976
Stop Year (derived)	1976

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	EXPLORATORY LAPAROTOMY
Start date (dd MMM yyyy)	UN UNK 1981
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	GUNSHOT WOUND
Start date (dd MMM yyyy)	UN UNK 1981
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

US3022031

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	BACK PAIN
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 (7)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	DEEP VEIN THROMBOSIS
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	SCHIZOAFFECTIVE DISORDER
Start date (dd MMM yyyy)	UN JUN 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	PTSD
Start date (dd MMM yyyy)	UN JAN 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	ALCOHOL DEPENDENCE
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	LUPUS ANTICOAGULANT POSITIVE
Start date (dd MMM yyyy)	UN UNK 1991
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 1991
Start Year (derived)	1991
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	HYPERCOAGULABLE STATE
Start date (dd MMM yyyy)	UN UNK 1991
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 1991
Start Year (derived)	1991
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	DVT
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	PULMONARY EMBOLISM
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1991
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	JAN 1991
Stop Year (derived)	1991

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	NIGHTMARES
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

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)	

US3022031

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3022031

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	27 JUL 2020
Time of assessment ( <i>00:00-23:59</i> )	17:25 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 17:25
Height ( <i>xxx.x</i> )	188 cm
Weight ( <i>xxx.x</i> )	88.6 kg
BMI ( <i>xxx.x</i> )	25.06790 kg/m <sup>2</sup>
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)	_____

US3022031

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

27 JUL 2020

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

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US3022031

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

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**Occupational Risk**

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**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**

IN SOCIAL SETTINGS AT RESTAURANTS AND SHOPPING MULTIPLE DAYS A WEEK

---

**Location and Living Circumstances Risk (check all that apply)**

---

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

PRODUCTION RELEASE (v12.003 EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 15:41:16

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

US3022031

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 27 JUL 2020

---

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

---

Folder OID VISIT1

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US3022031

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

What was the date of randomization? (dd MMM yyyy) 27 JUL 2020

What was the participant's randomization number? 184035

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



US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

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Height	ND - Not Done
Weight	ND - Not Done

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US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

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 ( <i>dd MMM yyyy</i> )	27 JUL 2020
Time of assessment ( <i>00:00-23:59</i> )	17:25 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 17:25
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	75 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

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 ( <i>dd MMM yyyy</i> )	27 JUL 2020
Time of assessment ( <i>00:00-23:59</i> )	19:58 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 19:58
Temperature ( <i>xxx.x</i> )	36.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	74 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

27 JUL 2020

---

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

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US3022031

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

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) 27 JUL 2020

What was the treatment time? (00:00-23:59) 19:11 (24 HR)

Treatment Date and Time (derived) 27 JUL 2020 19:11

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) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

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Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 27 JUL 2020

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Collection time (*00:00-23:59*) 18:05 (24 HR)

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Collection date and time (derived) 27 JUL 2020 18:05

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US3022031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

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Collection date ( <i>dd MMM yyyy</i> )			27 JUL 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:57	27 JUL 2020 17:57
Nasopharyngeal Swab 2	No		

---

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

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US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp 27 JUL 2020 19:58

PC Open Date & Time 27 JUL 2020 19:31

PC Close Date & Time 27 JUL 2020 22:01

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

**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**  
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 27 JUL 2020 22:56

PC Close Date & Time 28 JUL 2020 11:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:51

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.8 °F
Was any <b>MEDICATION TAKEN</b> 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 <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False
PC Time Stamp	29 JUL 2020 08:34
PC Open Date & Time	28 JUL 2020 12:00
PC Close Date & Time	29 JUL 2020 11:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:51

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	30 JUL 2020 09:39
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:51

**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  
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 30 JUL 2020 12:00  
PC Close Date & Time 31 JUL 2020 11:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.6 °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 False

PC Time Stamp 31 JUL 2020 22:52

PC Open Date & Time 31 JUL 2020 12:00

PC Close Date & Time 01 AUG 2020 11:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:51

**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  
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 01 AUG 2020 12:00  
PC Close Date & Time 02 AUG 2020 11:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:51

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	02 AUG 2020 17:38
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59



US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

**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

27 JUL 2020 19:53

PC Open Date & Time

27 JUL 2020 19:31

PC Close Date & Time

27 JUL 2020 22:01

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

**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

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

27 JUL 2020 22:56

PC Close Date & Time

28 JUL 2020 11:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 2

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	29 JUL 2020 08:35
PC Open Date & Time	28 JUL 2020 12:00
PC Close Date & Time	29 JUL 2020 11:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 3

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

30 JUL 2020 09:40

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 4

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

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 5

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

31 JUL 2020 22:52

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 6

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

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 7

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

02 AUG 2020 17:39

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59



US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

**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

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

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

No

Yes

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PC Time stamp	27 JUL 2020 19:55
PC Open Date & Time	27 JUL 2020 19:31
PC Close Date & Time	27 JUL 2020 22:01

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US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

**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

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

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

No

Yes

PC Time stamp

PC Open Date & Time

27 JUL 2020 22:56

PC Close Date & Time

28 JUL 2020 11:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:51

**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

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:51

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	Yes <input type="checkbox"/>
PC Time stamp	29 JUL 2020 08:36
PC Open Date & Time	28 JUL 2020 12:00
PC Close Date & Time	29 JUL 2020 11:59

---

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:51

**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

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:51

---

	Yes <input type="checkbox"/>
PC Time stamp	30 JUL 2020 09:40
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

---



US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:51

**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

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:51

Yes

---

PC Time stamp

---

PC Open Date & Time

30 JUL 2020 12:00

---

PC Close Date & Time

31 JUL 2020 11:59

---

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:51

**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

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:51

---

	Yes <input type="checkbox"/>
PC Time stamp	31 JUL 2020 22:53
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

---

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:51

**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

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:51

Yes

---

PC Time stamp

---

PC Open Date & Time

01 AUG 2020 12:00

---

PC Close Date & Time

02 AUG 2020 11:59

---

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:51

**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

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:51

Yes

---

PC Time stamp

---

PC Open Date & Time

02 AUG 2020 12:00

---

PC Close Date & Time

03 AUG 2020 11:59

---



US3022031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 05 AUG 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3022031

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3022031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 12 AUG 2020

---

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

---

Comments THREE TEMPTS WERE MADE.

---

*If Contact Not Made, please provide Comments*

---

US3022031

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3022031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 AUG 2020

---

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

---

Comments VM LEFT NUMEROUS TIMES

---

*If Contact Not Made, please provide Comments*

---

US3022031

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3022031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 29 SEP 2020

---

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

---

Folder OID VISIT2

---

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

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 ( <i>dd MMM yyyy</i> )	29 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:36 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 13:36
Temperature ( <i>xxx.x</i> )	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	82 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	73 mmHg
Diastolic Blood Pressure units	MMHG



US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

Timepoint Pre-Dose   
Post-Dose

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 \_\_\_\_\_

US3022031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

29 SEP 2020

---

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

---

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

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 DUE TO OVERDOSE OF MED

What was the study treatment? \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

What was the treatment time? (00:00-23:59) \_\_\_\_\_

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

US3022031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 29 SEP 2020

---

Collection time (*00:00-23:59*) 14:09 (24 HR)

---

Collection date and time (derived) 29 SEP 2020 14:09

---

US3022031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

---

Collection date ( <i>dd MMM yyyy</i> )			29 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:58	29 SEP 2020 13:58
Nasopharyngeal Swab 2	No		

---

US3022031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3022031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

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* \_\_\_\_\_

US3022031

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3022031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

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* \_\_\_\_\_

US3022031

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3022031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

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* \_\_\_\_\_

US3022031

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3022031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 28 OCT 2020

---

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

---

Folder OID VISIT3

---

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	28 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	14:00 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 14:00
Temperature ( <i>xxx.x</i> )	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	76 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3022031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

28 OCT 2020

---

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

---

US3022031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 28 OCT 2020

---

Collection time (*00:00-23:59*) 14:24 (24 HR)

---

Collection date and time (derived) 28 OCT 2020 14:24

---



US3022031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:41:16

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 SEP 2020 18:02:56
Patient Cloud Open Date & Time	26 SEP 2020 00:01
Patient Cloud Close Date & Time	30 SEP 2020 23:59

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 71

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

No

Yes

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

No

Yes

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

Date and time of submission	03 OCT 2020 19:46:54
Patient Cloud Open Date & Time	03 OCT 2020 00:01
Patient Cloud Close Date & Time	07 OCT 2020 23:59

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	10 OCT 2020 14:35:50
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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

Yes

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

No

Yes

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

Date and time of submission 26 OCT 2020 07:47:07

Patient Cloud Open Date & Time 24 OCT 2020 00:01

Patient Cloud Close Date & Time 28 OCT 2020 23:59

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 99

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

No

Yes

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

No

Yes

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

Date and time of submission 31 OCT 2020 17:24:01

Patient Cloud Open Date & Time 31 OCT 2020 00:01

Patient Cloud Close Date & Time 04 NOV 2020 23:59

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT** DAY 106

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

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

**US3022031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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

---

Date and time of submission

---

Patient Cloud Open Date & Time

07 NOV 2020 00:01

---

Patient Cloud Close Date & Time

11 NOV 2020 23:59

---



US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

TIMEPOINT	DAY 113
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"/>

**US3022031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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

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Date and time of submission

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Patient Cloud Open Date & Time

14 NOV 2020 00:01

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Patient Cloud Close Date & Time

18 NOV 2020 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 117

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

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 NOV 2020 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 21:55:41
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 13:46:07
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 09 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#) 13 DEC 2020 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 09:52:37
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 23 DEC 2020 09:51:24

Patient Cloud Open Date & Time 23 DEC 2020 00:01

Patient Cloud Close Date & Time 27 DEC 2020 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 DEC 2020 00:02:11
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 00:02:55
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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 13 JAN 2021 03:49:05

Patient Cloud Open Date & Time 13 JAN 2021 00:01

Patient Cloud Close Date & Time 17 JAN 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 06:56:54
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 17:11:56
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 00:01:52
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59



US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 00:02:21
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 00:01:57
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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 24 FEB 2021 00:02:06

Patient Cloud Open Date & Time 24 FEB 2021 00:01

Patient Cloud Close Date & Time 28 FEB 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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 06 MAR 2021 11:04:45

Patient Cloud Open Date & Time 03 MAR 2021 00:01

Patient Cloud Close Date & Time 07 MAR 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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 12 MAR 2021 11:30:54

Patient Cloud Open Date & Time 10 MAR 2021 00:01

Patient Cloud Close Date & Time 14 MAR 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 20:50:59
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 00:02:39
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 APR 2021 04:48:59
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59



US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 13:36:36
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 APR 2021 18:52:38
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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

Date and time of submission 21 APR 2021 13:32:12

Patient Cloud Open Date & Time 21 APR 2021 00:01

Patient Cloud Close Date & Time 25 APR 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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

Date and time of submission 28 APR 2021 02:02:21

Patient Cloud Open Date & Time 28 APR 2021 00:01

Patient Cloud Close Date & Time 02 MAY 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 299

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 MAY 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 MAY 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#) 06 JUN 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 320

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUN 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 334

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 23 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#) 27 JUN 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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  Yes

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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  Yes

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 AUG 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59



US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 390

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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  Yes

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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  Yes

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 OCT 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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   
Yes

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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  Yes

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#) 07 NOV 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 481

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 NOV 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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  Yes

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 NOV 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 DEC 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 DEC 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 DEC 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 22 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 26 DEC 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 JAN 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 530

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 FEB 2022 00:01
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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

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16 FEB 2022 00:01

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20 FEB 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3022031**

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

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06 MAR 2022 23:59

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US3022031

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**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

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US3022031

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**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   
Yes

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

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16 MAR 2022 00:01

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20 MAR 2022 23:59

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**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   
Yes

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

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23 MAR 2022 00:01

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27 MAR 2022 23:59

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US3022031

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**TIMEPOINT**

DAY 614

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

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US3022031

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**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  Yes

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

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

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10 APR 2022 23:59

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US3022031

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**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°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

**US3022031**

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**TIMEPOINT**

DAY 635

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3022031**

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US3022031

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Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

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27 APR 2022 00:01

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01 MAY 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

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04 MAY 2022 00:01

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08 MAY 2022 23:59

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**TIMEPOINT**

DAY 656

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 MAY 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 MAY 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 MAY 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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  Yes

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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  Yes

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUN 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 698

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3022031**

**Folder: New 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. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUN 2022 23:59

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US3022031

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Form: Safety Follow Up Diary

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**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

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**Generated On: 09 Jun 2021 14:49:51**

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59



US3022031

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Generated On: 09 Jun 2021 14:49:51

**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  Yes

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

**US3022031**

**Folder: New 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. I confirm I have read this message and will call the study clinic immediately

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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   
Yes

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUL 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:49:51**

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 27 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#) 31 JUL 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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   
Yes

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

**US3022031**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

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US3022031

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Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

---

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 761

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 768

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	31 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 SEP 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 SEP 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 SEP 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

---

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**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   
Yes

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

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

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

---

Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

---



US3022031

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:49:51

---

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 13:52:55

---

US3022031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 NOV 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3022031

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3022031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 DEC 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3022031

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3022031

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 25 JAN 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3022031

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3022031

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:54:26

Generated On: 09 Jun 2021 14:49:51

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 25 FEB 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---



US3022031

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:54:26

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3022031

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 23:00:05

Generated On: 09 Jun 2021 14:49:51

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 17 MAR 2021

---

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

---

Folder OID VISIT4

---

US3022031

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

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)	_____

US3022031

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 23:00:05

Generated On: 09 Jun 2021 14:49:51

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

17 MAR 2021

---

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

---

US3022031

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 23:00:05

Generated On: 09 Jun 2021 14:49:51

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	17 MAR 2021
Collection time ( <i>00:00-23:59</i> )	13:20 (24 HR)
Collection date and time (derived)	17 MAR 2021 13:20

---

US3022031

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 23:00:05

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3022031

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 23:00:05

Generated On: 09 Jun 2021 14:49:51

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 MAR 2021

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3022031

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 23:00:05

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3022031

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

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* \_\_\_\_\_

US3022031

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3022031

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:49:51

---

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

---

US3022031

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:49:51

---

Generate Next COVID-19 Assessment

Yes

No

---

US3022031

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 13 JAN 2021

---

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

---

Folder OID UNBLND\_DECIDE

---

US3022031

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 22:10:55

Generated On: 09 Jun 2021 14:49:51

Date of updated informed consent ( <i>dd MMM yyyy</i> )	13 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	13 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3022031

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

---

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

---

---

US3022031

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 13:50
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG



US3022031

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 16:00
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3022031

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

13 JAN 2021

---

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

---

US3022031

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

Was study treatment given? Yes   
No

If No, reason not given

Participant declined due to Adverse Event   
Physician withheld dose due to Adverse Event   
Death   
Lost To Follow-Up   
Physician Decision   
Pregnancy   
Protocol Deviation   
Study Terminated by Sponsor   
Withdrawal of Consent by Participant   
Confirmed COVID-19   
Other

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 13 JAN 2021

What was the treatment time? (00:00-23:59) 15:30 (24 HR)

Treatment Date and Time (derived) 13 JAN 2021 15:30

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

US3022031

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 13 JAN 2021

---

Collection time (*00:00-23:59*) 13:15 (24 HR)

---

Collection date and time (derived) 13 JAN 2021 13:15

---

US3022031

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 13 JAN 2021

---

Collection time (*00:00 - 23:59*) 13:26

---

Collection Date and Time (derived) 13 JAN 2021 13:26

---

US3022031

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3022031

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 JAN 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3022031

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:41:13

Generated On: 09 Jun 2021 14:49:51

---

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

---



US3022031

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

---

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	09 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	15:02 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 15:02
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> )	72 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3022031

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

---

Was the physical examination performed?

Yes

No

---

Date of examination (*dd MMM yyyy*)

09 FEB 2021

---

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

---

US3022031

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 09 FEB 2021

---

Collection time (*00:00-23:59*) 16:21 (24 HR)

---

Collection date and time (derived) 09 FEB 2021 16:21

---

US3022031

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

AEID USA-US051-2020-MRNA-1273-P30  
1000001

Adverse event OVERDOSE OF KLONOPIN

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 10 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy) 19 AUG 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 True

Hospital Admission Date (dd MMM yyyy) 10 AUG 2020

Hospital Discharge Date (dd MMM yyyy) 19 AUG 2020

Admitted to ICU? Yes   
No   
Unknown

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" 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	MEDICAL RECORDS OBTAINED FROM THE HOSPITAL. PATIENT WAS ADMITTED FOR OVERDOSE OF BENZODIAZEPINES CAUSING RESPIRATORY FAILURE.
Serious Adverse Event Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 15:41:11

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---

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 (2)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

AEID USA-US051-2020-MRNA-1273-P30  
1000001

Adverse event LUNG FAILURE

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 10 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy) 19 AUG 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 True

Hospital Admission Date (dd MMM yyyy) 10 AUG 2020

Hospital Discharge Date (dd MMM yyyy) 19 AUG 2020

Admitted to ICU? Yes   
No   
Unknown

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Feb 2021 15:41:11

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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	KLONAPIN OVERDOSE
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

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

AEID	USA-US051-2020-MRNA-1273-P30 1000001
Adverse event	PNUEMONIA
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)	10 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	19 AUG 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) 23 Feb 2021 15:41:11

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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	SAE DUE TO KLONAPIN OVERDOSE
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

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

---

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

Yes

No

---

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

---

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

Name of Medication ATORVASTATIN

Prophylaxis Yes   
No

Indication HYPERLIPIDEMIA

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 (1)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK	2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)	09 AUG	2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

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 (2)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN UNK 2019

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

Name of Medication OXYCODONE  
ACETAMINOPHEN

Prophylaxis Yes   
No

Indication BACK PAIN

Dose per administration 10/325

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

---

	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 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)	_____
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 (5)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

Name of Medication AOPIPIRAZOLE

Prophylaxis Yes   
No

Indication SCHIZOAFFECTIVE DISORDER

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

---

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*) 17 AUG 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

Name of Medication FLUOXETINE

Prophylaxis Yes   
No

Indication SCHIZOPHERNIA/ PTSD

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

---

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*) 17 AUG 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 15 JAN 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

Name of Medication RIVAROXABAN

Prophylaxis Yes   
No

Indication HYPERCOAGULABLE STABLES

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

	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 1991

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

Name of Medication DULOXETINE

Prophylaxis Yes   
No

Indication SCHIZOPHRENIA/PTSD

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

---

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*) 17 AUG 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

Name of Medication KLONOPIN

Prophylaxis Yes   
No

Indication ANXIETY

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

---

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 AUG 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 19 AUG 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

Name of Medication PRAZOSIN

Prophylaxis Yes   
No

Indication NIGHTMARES

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

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 JUN 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes   
No

Indication INFLUENZA PREVENTION

Dose per administration 0.5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

---

Intramuscular	<input checked="" type="radio"/>
Respiratory (Inhalation)	<input type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) UN SEP 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) UN SEP 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

Name of Medication DULOXETINE

Prophylaxis Yes   
No

Indication DEPRESSION

Dose per administration 30

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Feb 2021 15:41:11

Generated On: 09 Jun 2021 14:49:51

---

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*) 16 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Mar 2021 22:54:26

Generated On: 09 Jun 2021 14:49:51

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 AUG 2020	CT SCAN OF CHEST	Adverse Event	
10 AUG 2020	CHEST XRAY	Adverse Event	
10 AUG 2020	MECHANICAL VENTILATOR	Adverse Event	

US3022031

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Mar 2021 22:54:26

Generated On: 09 Jun 2021 14:49:51

---

Date of dosing discontinuation (dd MMM yyyy) 29 SEP 2020

---

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 AE#1

---

US3022031

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:49:51

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

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

SAEID	USA-US051-2020-MRNA-1273-P30 1000001
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

SAEID	USA-US051-2020-MRNA-1273-P30 1000001
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/AUG/2020 07:53
<b>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.</b>	True

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

SAEID	USA-US051-2020-MRNA-1273-P301000001
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/AUG/2020 09:53
<b>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.</b>	True

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

SAEID	USA-US051-2020-MRNA-1273-P30 1000001
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/OCT/2020 12:49
<b>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.</b>	True

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

SAEID	USA-US051-2020-MRNA-1273-P301000001
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/OCT/2020 15:26
<b>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.</b>	True

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

SAEID	USA-US051-2020-MRNA-1273-P301000001
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/NOV/2020 17:06
<b>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.</b>	True

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

SAEID	USA-US051-2020-MRNA-1273-P301000001
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	17/NOV/2020 08:17
<b>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.</b>	<input checked="" type="checkbox"/> True

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 23 Feb 2021 15:41:12

Generated On: 09 Jun 2021 14:49:51

SAEID	USA-US051-2020-MRNA-1273-P30 1000001
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	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	30/NOV/2020 09:38
<b>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.</b>	True

Audit

US3022031 (Prod: Meridian Clinical Research-Savannah)



**US3022031**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:49:51**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'US3022031'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 21:14:05

US3022031

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:12

US3022031

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '27 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 21:14:06

US3022031

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[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 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:12

US3022031

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'SCRN'	System	27 Jul 2020 23:42:12

US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '(b) (6)1953'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 21:14:07

US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered '66'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'YEARS'	System	27 Jul 2020 23:42:50



US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '66'	System	27 Jul 2020 23:43:09

US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'Male (M)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered '1'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50



US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered empty.	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:51

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:51

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered '27 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:09

US3022031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:51

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jul 2020'	System	27 Jul 2020 23:43:09

US3022031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:51

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '2020'	System	27 Jul 2020 23:43:09

US3022031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:51

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Amendment 1 (1)'	(b) (4) Shanice Bennett (b) (4)	27 Jul 2020 23:43:09



US3022031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:51

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:09

US3022031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:51

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered empty.	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:09

US3022031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:51

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered empty.	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:09

US3022031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:51

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:09

US3022031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:51

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 21:14:06

US3022031

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:51

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1'	System	27 Jul 2020 23:43:16

US3022031

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:49:51

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:16

US3022031

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:49:51

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:22



US3022031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:55:54
User closed query 'Per DM CLR: Hypertension was noted as a MH condition for this subject. However, the corresponding treatment was started prior to the start date of this condition. Please reconcile and update accordingly. Otherwise, clarify.' ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:52:33
Query 'Per DM CLR: Hypertension was noted as a MH condition for this subject. However, the corresponding treatment was started prior to the start date of this condition. Please reconcile and update accordingly. Otherwise, clarify.' ' answered with 'fixed' (Site from DM).	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 18:58:57
User opened query 'Per DM CLR: Hypertension was noted as a MH condition for this subject. However, the corresponding treatment was started prior to the start date of this condition. Please reconcile and update accordingly. Otherwise, clarify.' ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:13:23
User coded data point as SOC: Vascular disorders, HLG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 00:07:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 00:07:22
Data point term sent to Coder	System	28 Jul 2020 00:06:45
User entered 'hypertension'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:33

US3022031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)	
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17	
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)	14 Jan 2021 15:38:34
	(b) (4), (b) (6)		
User closed query 'Please confirm. Per source 2019.' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 15:38:32	
	(b) (4), (b) (6)		
Query 'Please confirm. Per source 2019.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 22:20:23	
User entered 'UN UNK 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 22:20:19	
User opened query 'Please confirm. Per source 2019.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 14:55:01	
User entered 'UN UNK 2015' reason for change: Data Entry Error	Stella Yoon (b) (4)	30 Sep 2020 18:58:52	
User entered 'un UNK 2020'	Stella Yoon (b) (4)	28 Jul 2020 00:06:33	
	(b) (4)		

US3022031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:55:58
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:33

US3022031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:55:59
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:33

US3022031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:02
User entered empty.	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:33

US3022031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:04
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:33

US3022031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 2019'	System	12 Nov 2020 22:20:19
User entered 'Jan 2015'	System	30 Sep 2020 18:58:52
User entered 'Jan 2020'	System	28 Jul 2020 00:06:33

US3022031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '2019'	System	12 Nov 2020 22:20:19
User entered '2015'	System	30 Sep 2020 18:58:52
User entered '2020'	System	28 Jul 2020 00:06:33



US3022031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	28 Jul 2020 00:06:33

US3022031

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	28 Jul 2020 00:06:33

US3022031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:10
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 00:07:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 00:07:22
Data point term sent to Coder	System	28 Jul 2020 00:06:44
User entered 'hyperlipidemia'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:43

US3022031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:12
User entered 'UN UNK 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 13:06:41
User entered 'un UNK 2020'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:43

US3022031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:14
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:43

US3022031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:16
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:43

US3022031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:18
User entered empty.	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:43

US3022031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:20
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:43



US3022031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 2019'	System	15 Oct 2020 13:06:41
User entered 'Jan 2020'	System	28 Jul 2020 00:06:43

US3022031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '2019'	System	15 Oct 2020 13:06:41
User entered '2020'	System	28 Jul 2020 00:06:43

US3022031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	28 Jul 2020 00:06:43

US3022031

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	28 Jul 2020 00:06:43

US3022031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:31
User closed query 'Per DM CLR: Please review this procedure and ensure that the underlying medical condition that led to this procedure is also recorded as a separate MH condition. Please update to record the underlying condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 14:36:51
Query 'Per DM CLR: Please review this procedure and ensure that the underlying medical condition that led to this procedure is also recorded as a separate MH condition. Please update to record the underlying condition as appropriate. Otherwise, clarify.' answered with 'boat injury' (Site from DM).	Stella Yoon (b) (4)	30 Sep 2020 18:58:29
User opened query 'Per DM CLR: Please review this procedure and ensure that the underlying medical condition that led to this procedure is also recorded as a separate MH condition. Please update to record the underlying condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:13:42
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Limb operation, LLT: Leg operation - version MedDRA\23.0.	Coder Import (b) (4)	28 Jul 2020 17:49:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Jul 2020 17:49:13
Data point term sent to Coder	System	28 Jul 2020 00:07:46
User entered 'right leg surgery'	Stella Yoon (b) (4)	28 Jul 2020 00:06:59

US3022031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:34
User entered 'un UNK 1976'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:59

US3022031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:35
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:59

US3022031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:38
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:59



US3022031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:40
User entered 'un UNK 1976'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:59

US3022031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:42
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:59

US3022031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 1976'	System	28 Jul 2020 00:06:59

US3022031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1976'	System	28 Jul 2020 00:06:59

US3022031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 1976'	System	28 Jul 2020 00:06:59

US3022031

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1976'	System	28 Jul 2020 00:06:59

US3022031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:48
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Abdominal therapeutic procedures NEC, PT: Explorative laparotomy, LLT: Explorative laparotomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 22:04:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 22:04:01
Data point term sent to Coder	System	28 Jul 2020 00:08:46
User entered 'exploratory laparotomy'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:07:49

US3022031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:49
User entered 'un UNK 1981'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:07:49



US3022031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:14
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:07:49

US3022031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:16
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:07:49

US3022031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:18
User entered 'un UNK 1981'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:07:49

US3022031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:20
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:07:49

US3022031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 1981'	System	28 Jul 2020 00:07:49

US3022031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1981'	System	28 Jul 2020 00:07:49

US3022031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 1981'	System	28 Jul 2020 00:07:49

US3022031

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1981'	System	28 Jul 2020 00:07:49



US3022031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:28
User coded data point as SOC: Injury, poisoning and procedural complications, HLGHT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Gun shot wound, LLT: Gun shot wound - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 22:37:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Jul 2020 22:37:57
Data point term sent to Coder	System	28 Jul 2020 00:08:46
User entered 'gunshot wound'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:01

US3022031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:31
User entered 'un UNK 1981'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:01

US3022031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:33
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:01

US3022031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:35
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:01

US3022031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:37
User entered 'un UNK 1981'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:01

US3022031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:39
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:01

US3022031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 1981'	System	28 Jul 2020 00:08:01

US3022031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1981'	System	28 Jul 2020 00:08:01



US3022031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:51

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 1981'	System	28 Jul 2020 00:08:01

US3022031

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1981'	System	28 Jul 2020 00:08:01

US3022031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 20:41:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 20:41:06
Data point term sent to Coder	System	05 Aug 2020 20:40:46
User entered 'BACK PAIN'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:40:45

US3022031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:48
User entered 'UN UNK 2012'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:40:45

US3022031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:51
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:40:45

US3022031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:53
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:40:45

US3022031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:55
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:40:45

US3022031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:58
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:40:45



US3022031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 2012'	System	05 Aug 2020 20:40:45

US3022031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '2012'	System	05 Aug 2020 20:40:45

US3022031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:51

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	05 Aug 2020 20:40:45

US3022031

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	05 Aug 2020 20:40:45

US3022031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Please confirm. This is not on MedHx per source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:38:53
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 15:38:51
Query 'Please confirm. This is not on MedHx per source.' answered with 'will update source ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 22:36:39
User opened query 'Please confirm. This is not on MedHx per source.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 15:05:23
User coded data point as SOC: Vascular disorders, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 19:01:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 19:01:57
Data point term sent to Coder	System	30 Sep 2020 19:00:34
User entered 'Deep vein thrombosis'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:00:22

US3022031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:38:55
	(b) (4), (b) (6)	
User entered 'un UNK 1991'	Stella Yoon (b) (4)	30 Sep 2020 19:00:22
	(b) (4)	

US3022031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:38:57
	(b) (4), (b) (6)	
User entered '0'	Stella Yoon (b) (4)	30 Sep 2020 19:00:22
	(b) (4)	

US3022031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	14 Jan 2021 15:38:59
User entered 'No (N)'	Stella Yoon (b) (4)	30 Sep 2020 19:00:22
	(b) (4)	



US3022031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:39:35
	(b) (4), (b) (6)	
User entered 'un UNK 1991'	Stella Yoon (b) (4)	30 Sep 2020 19:00:22
	(b) (4)	

US3022031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:39:37
	(b) (4), (b) (6)	
User entered '0'	Stella Yoon (b) (4)	30 Sep 2020 19:00:22
	(b) (4)	

US3022031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 1991'	System	30 Sep 2020 19:00:22

US3022031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1991'	System	30 Sep 2020 19:00:22

US3022031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 1991'	System	30 Sep 2020 19:00:22

US3022031

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1991'	System	30 Sep 2020 19:00:22

US3022031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:05:28
User coded data point as SOC: Psychiatric disorders, HLG: Schizophrenia and other psychotic disorders, HLT: Schizoaffective and schizophreniform disorders, PT: Schizoaffective disorder, LLT: Schizoaffective disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 19:06:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 19:06:49
Data point term sent to Coder	System	30 Sep 2020 19:05:54
User entered 'schizoaffective disorder'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:05:00

US3022031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Please confirm. Per source UNJan2007.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:39:50
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 15:39:44
Query 'Please confirm. Per source UNJan2007.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 22:25:18
User entered 'UN Jun 2007' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 22:25:14
User opened query 'Please confirm. Per source UNJan2007.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 15:05:42
User entered 'un Jun 2009'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:05:00



US3022031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:05:45
User entered '0'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:05:00

US3022031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:05:47
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:05:00

US3022031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:05:49
User entered empty.	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:05:00

US3022031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:05:51
User entered '0'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:05:00

US3022031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:51

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jun 2007'	System	12 Nov 2020 22:25:14
User entered 'Jun 2009'	System	30 Sep 2020 19:05:00

US3022031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '2007'	System	12 Nov 2020 22:25:14
User entered '2009'	System	30 Sep 2020 19:05:00

US3022031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	30 Sep 2020 19:05:00

US3022031

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	30 Sep 2020 19:05:00



US3022031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:06:08
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 16:41:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 16:41:34
Data point term sent to Coder	System	11 Nov 2020 16:40:25
User entered 'PTSD'	(b) (4), (b) (6)	11 Nov 2020 16:40:14

US3022031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:06:23
User entered 'UN Jan 2007'	(b) (4), (b) (6)	11 Nov 2020 16:40:14

US3022031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:06:31
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:40:14

US3022031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:40:14

US3022031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:06:36
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:40:14

US3022031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:06:43
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:40:14

US3022031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 2007'	System	11 Nov 2020 16:40:14

US3022031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '2007'	System	11 Nov 2020 16:40:14



US3022031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	11 Nov 2020 16:40:14

US3022031

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	11 Nov 2020 16:40:14

US3022031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as SOC: Psychiatric disorders, HLT: Substance related and addictive disorders, PT: Alcoholism, LLT: Alcohol dependence syndrome - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 18:33:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 18:33:45
Data point term sent to Coder	System	16 Nov 2020 18:33:11
User entered 'alcohol dependence'	(b) (4), (b) (6)	16 Nov 2020 18:33:02

US3022031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:02

US3022031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:02

US3022031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:02

US3022031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:02

US3022031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:02



US3022031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 2007'	System	16 Nov 2020 18:33:02

US3022031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '2007'	System	16 Nov 2020 18:33:02

US3022031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	16 Nov 2020 18:33:02

US3022031

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	16 Nov 2020 18:33:02

US3022031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as SOC: Investigations, HLT: Immunology and allergy investigations, HLT: Autoimmunity analyses, PT: Antiphospholipid antibodies positive, LLT: Lupus anticoagulant positive - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 18:49:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 18:49:45
Data point term sent to Coder	System	16 Nov 2020 18:34:12
User entered 'lupus anticoagulant positive'	(b) (4), (b) (6)	16 Nov 2020 18:33:34

US3022031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'un UNK 1991'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:34

US3022031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:34

US3022031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:34



US3022031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:34

US3022031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:34

US3022031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 1991'	System	16 Nov 2020 18:33:34

US3022031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1991'	System	16 Nov 2020 18:33:34

US3022031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	16 Nov 2020 18:33:34

US3022031

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	16 Nov 2020 18:33:34

US3022031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Coagulopathies and bleeding diatheses (excl thrombocytopenic), HLT: Coagulopathies, PT: Hypercoagulation, LLT: Hypercoagulation - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 18:34:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 18:34:46
Data point term sent to Coder	System	16 Nov 2020 18:34:12
User entered 'hypercoagulable state'	(b) (4), (b) (6)	16 Nov 2020 18:33:55

US3022031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'un UNK 1991'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:55



US3022031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:55

US3022031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:55

US3022031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:55

US3022031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:33:55

US3022031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 1991'	System	16 Nov 2020 18:33:55

US3022031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1991'	System	16 Nov 2020 18:33:55

US3022031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	16 Nov 2020 18:33:55

US3022031

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	16 Nov 2020 18:33:55



US3022031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as SOC: Vascular disorders, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: DVT - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 18:34:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 18:34:45
Data point term sent to Coder	System	16 Nov 2020 18:34:13
User entered 'dvt'	(b) (4), (b) (6)	16 Nov 2020 18:34:12

US3022031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'un UNK 1991'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:12

US3022031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:12

US3022031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:12

US3022031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'un UNK 1992'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:12

US3022031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:12

US3022031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 1991'	System	16 Nov 2020 18:34:12

US3022031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1991'	System	16 Nov 2020 18:34:12



US3022031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 1992'	System	16 Nov 2020 18:34:12

US3022031

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1992'	System	16 Nov 2020 18:34:12

US3022031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:08:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 20:08:13
Data point term sent to Coder	System	23 Nov 2020 18:01:59
User closed query 'DM-Coding: Please expand the reported abbreviation PE, entering the full text as the reported term.' (Site from System).	System	23 Nov 2020 18:01:25
Query 'DM-Coding: Please expand the reported abbreviation PE, entering the full text as the reported term.' answered with 'updated' (Site from System).	Morgan Deal (b) (4)	23 Nov 2020 18:01:25
User entered 'Pulmonary embolism' reason for change: Per Query Resolution	Morgan Deal (b) (4)	23 Nov 2020 18:01:19
User opened query 'DM-Coding: Please expand the reported abbreviation PE, entering the full text as the reported term.' (Site from System).	Coder Import (b) (4)	17 Nov 2020 10:22:55
Data point term sent to Coder	System	16 Nov 2020 18:35:13
User entered 'pe'	(b) (4), (b) (6)	16 Nov 2020 18:34:28

US3022031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'un UNK 1991'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:28

US3022031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:28

US3022031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:28

US3022031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'un UNK 1991'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:28

US3022031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:34:28



US3022031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 1991'	System	16 Nov 2020 18:34:28

US3022031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1991'	System	16 Nov 2020 18:34:28

US3022031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 1991'	System	16 Nov 2020 18:34:28

US3022031

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '1991'	System	16 Nov 2020 18:34:28

US3022031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:49:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Parasomnias, PT: Nightmare, LLT: Nightmares - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 18:35:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 18:35:45
Data point term sent to Coder	System	16 Nov 2020 18:35:14
User entered 'nightmares'	(b) (4), (b) (6)	16 Nov 2020 18:35:03

US3022031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:03

US3022031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:03

US3022031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:03



US3022031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:03

US3022031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:03

US3022031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 2007'	System	16 Nov 2020 18:35:03

US3022031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '2007'	System	16 Nov 2020 18:35:03

US3022031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	16 Nov 2020 18:35:03

US3022031

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	16 Nov 2020 18:35:03

US3022031

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:49:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Road traffic accident - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 10:29:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 10:29:55
Data point term sent to Coder	System	16 Nov 2020 18:36:14
User entered 'tractor trailer accident'	(b) (4), (b) (6)	16 Nov 2020 18:35:27

US3022031

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:27



US3022031

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:27

US3022031

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:27

US3022031

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:27

US3022031

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:35:27

US3022031

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 2007'	System	16 Nov 2020 18:35:27

US3022031

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '2007'	System	16 Nov 2020 18:35:27

US3022031

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 2007'	System	16 Nov 2020 18:35:27

US3022031

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '2007'	System	16 Nov 2020 18:35:27



US3022031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:49:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	11 Dec 2020 17:42:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Dec 2020 17:42:50
Data point term sent to Coder	System	11 Dec 2020 17:42:19
User entered 'anxiety'	(b) (4), (b) (6)	11 Dec 2020 17:42:17

US3022031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'un UNK 2007'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:42:17

US3022031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:42:17

US3022031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:42:17

US3022031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:42:17

US3022031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 17:42:17

US3022031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 2007'	System	11 Dec 2020 17:42:17

US3022031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '2007'	System	11 Dec 2020 17:42:17



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Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:49:51

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	11 Dec 2020 17:42:17

US3022031

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	11 Dec 2020 17:42:17

US3022031

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:49:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18

US3022031

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18

US3022031

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18

US3022031

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18

US3022031

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18

US3022031

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:49:51

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18



US3022031

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18

US3022031

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18

US3022031

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:49:51

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18

US3022031

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18

US3022031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:49:51

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as SOC: Psychiatric disorders, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 18:36:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 18:36:54
Data point term sent to Coder	System	26 Jan 2021 18:35:49
User entered 'DEPRESSION'	(b) (4), (b) (6)	26 Jan 2021 18:35:21

US3022031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:49:51

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'UN UNK 2007'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:35:21

US3022031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:35:21

US3022031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:49:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Jan 2021 18:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Jan 2021 18:35:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 18:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 18:35:21
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 18:35:21



US3022031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:49:51

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:35:21

US3022031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:49:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:35:21

US3022031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:49:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'Jan 2007'	System	26 Jan 2021 18:35:21

US3022031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:49:51

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '2007'	System	26 Jan 2021 18:35:21

US3022031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:49:51

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	26 Jan 2021 18:35:21

US3022031

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 14:49:51

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered empty.	System	26 Jan 2021 18:35:21

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:57

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '27 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:57



US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '17:25'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:57

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered '27 Jul 2020 17:25'	System	28 Jul 2020 00:08:57

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '188' cm	(b) (4) Stella Yoon (b) (4)	28 Jul 2020 00:08:57
DataPoint set to visible.	(b) (4) System	27 Jul 2020 23:43:16

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '88.6' kg	(b) (4) Stella Yoon (b) (4)	28 Jul 2020 00:08:57
DataPoint set to visible.	(b) (4) System	27 Jul 2020 23:43:16

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
Amendment Manager: User entered '25.06790'	System	16 Sep 2020 23:37:04
User entered '25.1'	System	28 Jul 2020 00:08:57
DataPoint set to visible.	System	27 Jul 2020 23:43:16

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'kg/m2'	System	28 Jul 2020 00:08:57
DataPoint set to visible.	System	27 Jul 2020 23:43:16

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 07:29:06
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:16:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:16:08
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:37:19
User entered '36.7' C	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:57

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:16:08
User entered 'Oral (Oral)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:57



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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:57

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	03 Nov 2020 15:16:08
User entered '75'	Morgan Deal (b) (4)	03 Nov 2020 15:16:08
	(b) (4)	
	Stella Yoon (b) (4)	28 Jul 2020 00:08:57
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'bpm'	System	28 Jul 2020 00:08:57

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:16:08
User entered '14'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:57

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'breaths/min'	System	28 Jul 2020 00:08:57

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	03 Nov 2020 15:16:08
User entered '123'	Morgan Deal (b) (4)	03 Nov 2020 15:16:08
	(b) (4)	
	Stella Yoon (b) (4)	28 Jul 2020 00:08:57
	(b) (4)	

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'mmHg'	System	28 Jul 2020 00:08:57

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:16:08
User entered '72'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:57



US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User entered 'mmHg'	System	28 Jul 2020 00:08:57

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18

US3022031

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:01

US3022031

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '27 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:01

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

[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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

[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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

**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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34



US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

**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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

[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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

[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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

**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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

[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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

[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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

**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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

**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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34



US3022031

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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'in sociAL settings at restaurants and shopping multiple days a week'	(b) (4) Stella Yoon (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

[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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

[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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

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 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '1'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:51

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:07:18
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Resident in a community with ongoing person to person transmission'	(b) (4) Stella Yoon (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 09:42:51
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'edc is entered for visit 2' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:21:37
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:44:10
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:41

US3022031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '27 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:41

US3022031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[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 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Clinic (Clinic)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:41

US3022031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'VISIT1'	System	28 Jul 2020 00:09:41

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '27 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 22:19:08

US3022031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:51

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:04:45
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:04:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Jul 2020 22:19:08
User entered '184035' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 22:19:08



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:51

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 22:19:08

US3022031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:51

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 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:52

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:51

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 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:52

US3022031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:51

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:52

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:51

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:52

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:51

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:52

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 07:28:46
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:15:24
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:15:17
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:40:37
User entered '188' cm	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:15:17
User entered '88.6' kg	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 07:28:46
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:15:24
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:15:17
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:40:37
User entered '188' cm	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:15:17
User entered '88.6' kg	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User accepted default value 'Pre-Dose (PREDOSE)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '27 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '17:25'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '27 Jul 2020 17:25'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '36.7' C	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Oral (Oral)'	(b) (4) Stella Yoon (b) (4)	28 Jul 2020 00:10:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '75'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'bpm'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '14'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'breaths/min'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '123'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'mmHg'	System	28 Jul 2020 00:10:59



US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '72'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'mmHg'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 07:28:46
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:15:24
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:15:17
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:40:37
User entered '188' cm	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 15:15:17
User entered '88.6' kg	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User accepted default value 'Post-Dose (POSTDOSE)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '27 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	03 Aug 2020 18:39:53
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol, 30 minutes after vaccination' (Site from System).	(b) (4), (b) (6)	28 Jul 2020 00:12:09
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	Stella Yoon (b) (4)	28 Jul 2020 00:10:59
User entered '19:58'	Stella Yoon (b) (4)	28 Jul 2020 00:10:59



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '27 Jul 2020 19:58'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '36.2' C	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Oral (Oral)'	(b) (4) Stella Yoon (b) (4)	28 Jul 2020 00:10:59
	(b) (4)	

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '74'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'bpm'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '16'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'breaths/min'	System	28 Jul 2020 00:10:59



US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '128'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'mmHg'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '72'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'mmHg'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4)	28 Jul 2020 00:12:18
	(b) (4)	

US3022031

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '27 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:18

US3022031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:52

US3022031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered empty.	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:52



US3022031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

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 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) Shanice Bennett (b) (4)	27 Jul 2020 23:43:52

US3022031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'MRNA-1273 OR PLACEBO'	System	27 Jul 2020 23:43:52

US3022031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '27 Jul 2020'	(b) (4) Shanice Bennett (b) (4)	27 Jul 2020 23:43:52

US3022031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered '19:11'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:52

US3022031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '27 Jul 2020 19:11'	System	27 Jul 2020 23:43:52

US3022031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'Left Arm (LEFT ARM)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:52

US3022031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'ONCE'	System	27 Jul 2020 23:43:52

US3022031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'INTRAMUSCULAR'	System	27 Jul 2020 23:43:52



US3022031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:45

US3022031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '27 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:45

US3022031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '18:05'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:45

US3022031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '27 Jul 2020 18:05'	System	28 Jul 2020 00:12:45

US3022031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:49:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated (02OCT2020) is reported under Visit 2 Day 29 in PPD central lab, however Central Laboratory - Nasopharyngeal Swab form is not completed in EDC. Please complete, else clarify the correct visit. Thank you.' (Site from DM).	(b) (4)	24 Nov 2020 09:22:40
Query 'Per GCL Lab Reconciliation: Swab: Sample dated (02OCT2020) is reported under Visit 2 Day 29 in PPD central lab, however Central Laboratory - Nasopharyngeal Swab form is not completed in EDC. Please complete, else clarify the correct visit. Thank you.' answered with 'visit 1 is correct 27jul2020' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 21:32:55
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated (02OCT2020) is reported under Visit 2 Day 29 in PPD central lab, however Central Laboratory - Nasopharyngeal Swab form is not completed in EDC. Please complete, else clarify the correct visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 10:59:25
User entered '27 Jul 2020'	Stella Yoon (b) (4)	28 Jul 2020 00:12:53

US3022031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:53

US3022031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4)	28 Jul 2020 00:12:53
	(b) (4)	

US3022031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '17:57'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:53



US3022031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '27 Jul 2020 17:57'	System	28 Jul 2020 00:12:53

US3022031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:53

US3022031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:53

US3022031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:53

US3022031

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered empty.	System	28 Jul 2020 00:12:53

US3022031

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4)	28 Jul 2020 00:12:56
	(b) (4)	

US3022031

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '1'	System	28 Jul 2020 00:12:56

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Jul 2020 23:43:52



US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:57:40', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c66f7bad-b840-4647-88ad-bd506b67b50a'	System	27 Jul 2020 23:58:18
User entered 'Yes (Y)'	System	27 Jul 2020 23:58:18

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:57:57', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c66f7bad-b840-4647-88ad-bd506b67b50a'	System	27 Jul 2020 23:58:18
User entered '97.2'	System	27 Jul 2020 23:58:18

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:58:04', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c66f7bad-b840-4647-88ad-bd506b67b50a'	System	27 Jul 2020 23:58:18
User entered 'No (N)'	System	27 Jul 2020 23:58:18

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:58:12', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c66f7bad-b840-4647-88ad-bd506b67b50a'	System	27 Jul 2020 23:58:18
User entered '27 Jul 2020 19:58'	System	27 Jul 2020 23:58:18

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '27 Jul 2020 19:31'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '27 Jul 2020 22:01'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 1, after vaccination (at home)'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59



US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '27 Jul 2020 22:56'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '28 Jul 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 2'	System	27 Jul 2020 23:43:52



US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:33:06', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '5dd04919-5929-4360-a0a2-3f30bd74a262'	System	29 Jul 2020 12:34:32
User entered 'Yes (Y)'	System	29 Jul 2020 12:34:32

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:51

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:33:53', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '5dd04919-5929-4360-a0a2-3f30bd74a262'	System	29 Jul 2020 12:34:32
User entered '97.8'	System	29 Jul 2020 12:34:32

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:34:01', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '5dd04919-5929-4360-a0a2-3f30bd74a262'	System	29 Jul 2020 12:34:32
User entered 'Yes (Y)'	System	29 Jul 2020 12:34:32

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
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 'TOOK MEDICATION FOR BACK PAIN NOT SOLICITED EVENT ' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 15:28:38
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.'	Shanice Bennett (b) (4)	05 Aug 2020 20:39:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:34:15', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '5dd04919-5929-4360-a0a2-3f30bd74a262'	System	29 Jul 2020 12:34:32
User entered '1'	System	29 Jul 2020 12:34:32

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:51

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:34:15', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '5dd04919-5929-4360-a0a2-3f30bd74a262'	System	29 Jul 2020 12:34:32
User entered '0'	System	29 Jul 2020 12:34:32

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:34:29', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '5dd04919-5929-4360-a0a2-3f30bd74a262'	System	29 Jul 2020 12:34:32
User entered '29 Jul 2020 08:34'	System	29 Jul 2020 12:34:32

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '28 Jul 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '29 Jul 2020 11:59'	System	27 Jul 2020 23:43:52



US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 3'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:39:04', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '39b920d6-3ca6-46fa-8834-55c8bf582ca9'	System	30 Jul 2020 13:39:36
User entered 'Yes (Y)'	System	30 Jul 2020 13:39:36

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:39:18', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '39b920d6-3ca6-46fa-8834-55c8bf582ca9'	System	30 Jul 2020 13:39:36
User entered '97.0'	System	30 Jul 2020 13:39:36

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:39:23', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '39b920d6-3ca6-46fa-8834-55c8bf582ca9'	System	30 Jul 2020 13:39:36
User entered 'No (N)'	System	30 Jul 2020 13:39:36

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:39:31', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '39b920d6-3ca6-46fa-8834-55c8bf582ca9'	System	30 Jul 2020 13:39:36
User entered '30 Jul 2020 09:39'	System	30 Jul 2020 13:39:36

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '29 Jul 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '30 Jul 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 4'	System	27 Jul 2020 23:43:52



US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:51

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '30 Jul 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '31 Jul 2020 11:59'	System	27 Jul 2020 23:43:52



US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 5'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:51:13', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c9caf001-8ac9-4c73-87e5-360b7502798c'	System	01 Aug 2020 02:52:11
User entered 'Yes (Y)'	System	01 Aug 2020 02:52:11

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:51:41', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c9caf001-8ac9-4c73-87e5-360b7502798c'	System	01 Aug 2020 02:52:11
User entered '98.6'	System	01 Aug 2020 02:52:11

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:51:48', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c9caf001-8ac9-4c73-87e5-360b7502798c'	System	01 Aug 2020 02:52:11
User entered 'Yes (Y)'	System	01 Aug 2020 02:52:11

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
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 'TOOK MEDICATION FOR BACK PAIN NOT SOLICITED EVENT' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 15:28:53
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 'TOOK MEDICATION FOR BACK PAIN NOT SOLICITED EVENT' (Site from System).	Shanice Bennett (b) (4)	05 Aug 2020 20:40:19
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).	System	01 Aug 2020 02:52:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:51:59', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c9caf001-8ac9-4c73-87e5-360b7502798c'	System	01 Aug 2020 02:52:11
User entered '1'	System	01 Aug 2020 02:52:11

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:51

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:51:59', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c9caf001-8ac9-4c73-87e5-360b7502798c'	System	01 Aug 2020 02:52:11
User entered '0'	System	01 Aug 2020 02:52:11

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:52:08', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c9caf001-8ac9-4c73-87e5-360b7502798c'	System	01 Aug 2020 02:52:11
User entered '31 Jul 2020 22:52'	System	01 Aug 2020 02:52:11

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '31 Jul 2020 12:00'	System	27 Jul 2020 23:43:52



US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '01 Aug 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 6'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:51

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59



US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '01 Aug 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '02 Aug 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 7'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-08-02T17:38:27', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '98da796b-b3d1-4357-be4e-4483a665cce6'	System	02 Aug 2020 21:38:57
User entered 'Yes (Y)'	System	02 Aug 2020 21:38:57

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-08-02T17:38:42', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '98da796b-b3d1-4357-be4e-4483a665cce6'	System	02 Aug 2020 21:38:57
User entered '97.7'	System	02 Aug 2020 21:38:57

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-08-02T17:38:47', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '98da796b-b3d1-4357-be4e-4483a665cce6'	System	02 Aug 2020 21:38:57
User entered 'No (N)'	System	02 Aug 2020 21:38:57

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-08-02T17:38:54', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '98da796b-b3d1-4357-be4e-4483a665cce6'	System	02 Aug 2020 21:38:57
User entered '02 Aug 2020 17:38'	System	02 Aug 2020 21:38:57

US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '02 Aug 2020 12:00'	System	27 Jul 2020 23:43:52



US3022031

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '03 Aug 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:53:43', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '652b6ea9-cf82-49e5-aaee-17e4768477a9'	System	27 Jul 2020 23:54:00
User entered 'None (1)'	System	27 Jul 2020 23:54:00

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:53:16', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '652b6ea9-cf82-49e5-aaee-17e4768477a9'	System	27 Jul 2020 23:54:00
User entered 'No (N)'	System	27 Jul 2020 23:54:00

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:53:20', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '652b6ea9-cf82-49e5-aace-17e4768477a9'	System	27 Jul 2020 23:54:00
User entered 'No (N)'	System	27 Jul 2020 23:54:00

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:53:29', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '652b6ea9-cf82-49e5-aaee-17e4768477a9'	System	27 Jul 2020 23:54:00
User entered 'None (1)'	System	27 Jul 2020 23:54:00

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:53:56', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '652b6ea9-cf82-49e5-aaee-17e4768477a9'	System	27 Jul 2020 23:54:00
User entered '27 Jul 2020 19:53'	System	27 Jul 2020 23:54:00

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '27 Jul 2020 19:31'	System	27 Jul 2020 23:43:52



US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '27 Jul 2020 22:01'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 1, after vaccination (at home)'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59



US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '27 Jul 2020 22:56'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '28 Jul 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 2'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:34:40', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'e46684e7-5768-4b14-8c18-37aaf8051833'	System	29 Jul 2020 12:35:19
User entered 'None (1)'	System	29 Jul 2020 12:35:19

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:34:45', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'e46684e7-5768-4b14-8c18-37aaf8051833'	System	29 Jul 2020 12:35:19
User entered 'No (N)'	System	29 Jul 2020 12:35:19

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:34:50', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'e46684e7-5768-4b14-8c18-37aaf8051833'	System	29 Jul 2020 12:35:19
User entered 'No (N)'	System	29 Jul 2020 12:35:19

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:34:59', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'e46684e7-5768-4b14-8c18-37aaf8051833'	System	29 Jul 2020 12:35:19
User entered 'None (1)'	System	29 Jul 2020 12:35:19



US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:35:15', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'e46684e7-5768-4b14-8c18-37aaf8051833'	System	29 Jul 2020 12:35:19
User entered '29 Jul 2020 08:35'	System	29 Jul 2020 12:35:19

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '28 Jul 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '29 Jul 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 3'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:39:41', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c54c1fc7-000f-4c12-a7da-59e227f7baae'	System	30 Jul 2020 13:40:10
User entered 'None (1)'	System	30 Jul 2020 13:40:10

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:40:02', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c54c1fc7-000f-4c12-a7da-59e227f7baae'	System	30 Jul 2020 13:40:10
User entered 'No (N)'	System	30 Jul 2020 13:40:10

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:39:50', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c54c1fc7-000f-4c12-a7da-59e227f7baae'	System	30 Jul 2020 13:40:10
User entered 'No (N)'	System	30 Jul 2020 13:40:10

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:39:56', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c54c1fc7-000f-4c12-a7da-59e227f7baae'	System	30 Jul 2020 13:40:10
User entered 'None (1)'	System	30 Jul 2020 13:40:10



US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:40:06', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c54c1fc7-000f-4c12-a7da-59e227f7baae'	System	30 Jul 2020 13:40:10
User entered '30 Jul 2020 09:40'	System	30 Jul 2020 13:40:10

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '29 Jul 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '30 Jul 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 4'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:51

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59



US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:51

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '30 Jul 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '31 Jul 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 5'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:52:15', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '70ee4ac5-93cc-484b-8fd4-918f9d36a2f3'	System	01 Aug 2020 02:52:38
User entered 'None (1)'	System	01 Aug 2020 02:52:38

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:52:19', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '70ee4ac5-93cc-484b-8fd4-918f9d36a2f3'	System	01 Aug 2020 02:52:38
User entered 'No (N)'	System	01 Aug 2020 02:52:38



US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:52:24', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '70ee4ac5-93cc-484b-8fd4-918f9d36a2f3'	System	01 Aug 2020 02:52:38
User entered 'No (N)'	System	01 Aug 2020 02:52:38

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:52:29', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '70ee4ac5-93cc-484b-8fd4-918f9d36a2f3'	System	01 Aug 2020 02:52:38
User entered 'None (1)'	System	01 Aug 2020 02:52:38

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:52:35', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '70ee4ac5-93cc-484b-8fd4-918f9d36a2f3'	System	01 Aug 2020 02:52:38
User entered '31 Jul 2020 22:52'	System	01 Aug 2020 02:52:38

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '31 Jul 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '01 Aug 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 6'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59



US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:51

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:51

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '01 Aug 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '02 Aug 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 7'	System	27 Jul 2020 23:43:52



US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-08-02T17:39:01', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '86a60ad4-63a7-43d5-a096-b1cd4a022407'	System	02 Aug 2020 21:39:32
User entered 'None (1)'	System	02 Aug 2020 21:39:32

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-08-02T17:39:06', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '86a60ad4-63a7-43d5-a096-b1cd4a022407'	System	02 Aug 2020 21:39:32
User entered 'No (N)'	System	02 Aug 2020 21:39:32

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-08-02T17:39:10', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '86a60ad4-63a7-43d5-a096-b1cd4a022407'	System	02 Aug 2020 21:39:32
User entered 'No (N)'	System	02 Aug 2020 21:39:32

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-08-02T17:39:15', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '86a60ad4-63a7-43d5-a096-b1cd4a022407'	System	02 Aug 2020 21:39:32
User entered 'None (1)'	System	02 Aug 2020 21:39:32

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-08-02T17:39:29', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '86a60ad4-63a7-43d5-a096-b1cd4a022407'	System	02 Aug 2020 21:39:32
User entered '02 Aug 2020 17:39'	System	02 Aug 2020 21:39:32

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '02 Aug 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '03 Aug 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Jul 2020 23:43:52



US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:54:11', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'edf98898-9c07-4cba-b66b-a461d8db880b'	System	27 Jul 2020 23:55:05
User entered 'None (0)'	System	27 Jul 2020 23:55:05

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:54:20', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'edf98898-9c07-4cba-b66b-a461d8db880b'	System	27 Jul 2020 23:55:05
User entered 'None (0)'	System	27 Jul 2020 23:55:05

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:54:24', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'edf98898-9c07-4cba-b66b-a461d8db880b'	System	27 Jul 2020 23:55:05
User entered 'None (0)'	System	27 Jul 2020 23:55:05

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:54:29', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'edf98898-9c07-4cba-b66b-a461d8db880b'	System	27 Jul 2020 23:55:05
User entered 'None (0)'	System	27 Jul 2020 23:55:05

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:54:34', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'edf98898-9c07-4cba-b66b-a461d8db880b'	System	27 Jul 2020 23:55:05
User entered 'None (0)'	System	27 Jul 2020 23:55:05

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:54:39', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'edf98898-9c07-4cba-b66b-a461d8db880b'	System	27 Jul 2020 23:55:05
User entered 'None (0)'	System	27 Jul 2020 23:55:05

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:54:48', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'edf98898-9c07-4cba-b66b-a461d8db880b'	System	27 Jul 2020 23:55:05
User entered 'No (N)'	System	27 Jul 2020 23:55:05

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-27T19:55:02', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'edf98898-9c07-4cba-b66b-a461d8db880b' User entered '27 Jul 2020 19:55'	System	27 Jul 2020 23:55:05
	System	27 Jul 2020 23:55:05



US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '27 Jul 2020 19:31'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '27 Jul 2020 22:01'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 1, after vaccination (at home)'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59



US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

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)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '27 Jul 2020 22:56'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '28 Jul 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 2'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:35:27', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'fda6446a-9e58-4e24-9c8d-3ce1638f1cdc'	System	29 Jul 2020 12:36:19
User entered 'None (0)'	System	29 Jul 2020 12:36:19

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:35:32', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'fda6446a-9e58-4e24-9c8d-3ce1638f1cdc' User entered 'None (0)'	System	29 Jul 2020 12:36:19
	System	29 Jul 2020 12:36:19



US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:35:38', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'fda6446a-9e58-4e24-9c8d-3ce1638f1cdc'	System	29 Jul 2020 12:36:19
User entered 'None (0)'	System	29 Jul 2020 12:36:19

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:35:45', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'fda6446a-9e58-4e24-9c8d-3ce1638f1cdc' User entered 'None (0)'	System	29 Jul 2020 12:36:19
	System	29 Jul 2020 12:36:19

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:35:51', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'fda6446a-9e58-4e24-9c8d-3ce1638f1cdc'	System	29 Jul 2020 12:36:19
User entered 'None (0)'	System	29 Jul 2020 12:36:19

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:35:57', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'fda6446a-9e58-4e24-9c8d-3ce1638f1cdc'	System	29 Jul 2020 12:36:19
User entered 'None (0)'	System	29 Jul 2020 12:36:19

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:51

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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:36:04', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'fda6446a-9e58-4e24-9c8d-3ce1638f1cdc'	System	29 Jul 2020 12:36:19
User entered 'No (N)'	System	29 Jul 2020 12:36:19

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-29T08:36:17', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'fda6446a-9e58-4e24-9c8d-3ce1638f1cdc' User entered '29 Jul 2020 08:36'	System	29 Jul 2020 12:36:19
	System	29 Jul 2020 12:36:19

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '28 Jul 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '29 Jul 2020 11:59'	System	27 Jul 2020 23:43:52



US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 3'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:40:17', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '9f04e71a-0b01-4f01-8b29-d36a52994f82'	System	30 Jul 2020 13:40:50
User entered 'None (0)'	System	30 Jul 2020 13:40:50

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:40:21', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '9f04e71a-0b01-4f01-8b29-d36a52994f82'	System	30 Jul 2020 13:40:50
User entered 'None (0)'	System	30 Jul 2020 13:40:50

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:40:25', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '9f04e71a-0b01-4f01-8b29-d36a52994f82'	System	30 Jul 2020 13:40:50
User entered 'None (0)'	System	30 Jul 2020 13:40:50

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:40:30', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '9f04e71a-0b01-4f01-8b29-d36a52994f82'	System	30 Jul 2020 13:40:50
User entered 'None (0)'	System	30 Jul 2020 13:40:50

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:40:33', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '9f04e71a-0b01-4f01-8b29-d36a52994f82'	System	30 Jul 2020 13:40:50
User entered 'None (0)'	System	30 Jul 2020 13:40:50

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:40:37', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '9f04e71a-0b01-4f01-8b29-d36a52994f82'	System	30 Jul 2020 13:40:50
User entered 'None (0)'	System	30 Jul 2020 13:40:50

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:51

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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:40:42', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '9f04e71a-0b01-4f01-8b29-d36a52994f82'	System	30 Jul 2020 13:40:50
User entered 'No (N)'	System	30 Jul 2020 13:40:50



US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-30T09:40:47', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '9f04e71a-0b01-4f01-8b29-d36a52994f82'	System	30 Jul 2020 13:40:50
User entered '30 Jul 2020 09:40'	System	30 Jul 2020 13:40:50

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '29 Jul 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '30 Jul 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 4'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59



US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:51

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)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '30 Jul 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '31 Jul 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 5'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:52:44', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '1bfd5854-d6e1-4287-8c30-ff92d9fdfea3'	System	01 Aug 2020 02:53:21
User entered 'None (0)'	System	01 Aug 2020 02:53:21



US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:52:49', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '1bfd5854-d6e1-4287-8c30-ff92d9fdfea3'	System	01 Aug 2020 02:53:21
User entered 'None (0)'	System	01 Aug 2020 02:53:21

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:52:53', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '1bfd5854-d6e1-4287-8c30-ff92d9fdfea3'	System	01 Aug 2020 02:53:21
User entered 'None (0)'	System	01 Aug 2020 02:53:21

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:52:57', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '1bfd5854-d6e1-4287-8c30-ff92d9fdfea3'	System	01 Aug 2020 02:53:21
User entered 'None (0)'	System	01 Aug 2020 02:53:21

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:53:01', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '1bfd5854-d6e1-4287-8c30-ff92d9fdfea3'	System	01 Aug 2020 02:53:21
User entered 'None (0)'	System	01 Aug 2020 02:53:21

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:53:05', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '1bfd5854-d6e1-4287-8c30-ff92d9fdfea3'	System	01 Aug 2020 02:53:21
User entered 'None (0)'	System	01 Aug 2020 02:53:21

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:51

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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:53:09', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '1bfd5854-d6e1-4287-8c30-ff92d9fdfea3'	System	01 Aug 2020 02:53:21
User entered 'No (N)'	System	01 Aug 2020 02:53:21

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-07-31T22:53:17', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '1bfd5854-d6e1-4287-8c30-ff92d9fdfea3'	System	01 Aug 2020 02:53:21
User entered '31 Jul 2020 22:53'	System	01 Aug 2020 02:53:21

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '31 Jul 2020 12:00'	System	27 Jul 2020 23:43:52



US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '01 Aug 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 6'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59



US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:51

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)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '01 Aug 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '02 Aug 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 7'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:51

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:51

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:51

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59



US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:51

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:51

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:51

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:51

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)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '02 Aug 2020 12:00'	System	27 Jul 2020 23:43:52

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:49:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
User entered '03 Aug 2020 11:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 19:00:33



US3022031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered '05 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 19:00:33

US3022031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 19:00:33

US3022031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) Shanice Bennett (b) (4)	25 Aug 2020 19:00:33
	(b) (4)	

US3022031

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 19:00:37

US3022031

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '1'	System	25 Aug 2020 19:00:37

US3022031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per GCL Lab Rec: it appears GCL has a Nasopharyngeal Swab with date of 02OCT2020 as Day 29; however, it appears Day 29 did not occur. Please clarify' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:59:08
Query 'Per GCL Lab Rec: it appears GCL has a Nasopharyngeal Swab with date of 02OCT2020 as Day 29; however, it appears Day 29 did not occur. Please clarify' answered with 'visit 2 entered ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 19:21:18
User opened query 'Per GCL Lab Rec: it appears GCL has a Nasopharyngeal Swab with date of 02OCT2020 as Day 29; however, it appears Day 29 did not occur. Please clarify' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 17:16:15
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	25 Aug 2020 19:01:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	25 Aug 2020 19:01:12
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	25 Aug 2020 19:00:53
User entered 'No (N)'	Shanice Bennett (b) (4)	25 Aug 2020 19:00:53

US3022031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Aug 2020 19:01:03
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	25 Aug 2020 19:01:03
User entered '12 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 19:01:03
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Aug 2020 19:00:53
User entered '14 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 19:00:53

US3022031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'Contact Not Made (CONTACT NOT MADE)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 19:00:53



US3022031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System (b) (4)	25 Aug 2020 19:01:55
User entered 'Three tempts were made.' reason for change: Data Entry Error	Shanice Bennett (b) (4)	25 Aug 2020 19:01:55
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System (b) (4)	25 Aug 2020 19:00:53
User entered empty.	Shanice Bennett (b) (4)	25 Aug 2020 19:00:53

US3022031

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 11:39:51
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Subject is participating and continuing ' (Site from DM).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 21:14:01
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2OCT2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 10:49:28
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 19:02:00

US3022031

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '1'	System	25 Aug 2020 19:02:00

US3022031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:29:36

US3022031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 04:30:36
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'THIS IS CORRECT' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 16:29:51
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Nov 2020 16:29:36
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Nov 2020 16:29:36

US3022031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:29:36

US3022031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'VM LEFT NUMEROUS TIMES'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:29:36

US3022031

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:29:41



US3022031

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'I'	System	11 Nov 2020 16:29:41

US3022031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:30:03

US3022031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
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)	13 Nov 2020 14:36:31
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'this date is correct' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 22:21:26
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	11 Nov 2020 16:30:03
User entered '29 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 16:30:03

US3022031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[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 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:30:03

US3022031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'VISIT2'	System	11 Nov 2020 16:30:03

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:30:33



US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '13:36'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '29 Sep 2020 13:36'	System	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '82'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'bpm'	System	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '15'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:30:33



US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'breaths/min'	System	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '128'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'mmHg'	System	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '73'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'mmHg'	System	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Nov 2020 22:22:25

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per CDM, re-query: If the vitals were not assessed, then please answer with "No" to the question in this field. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 09:05:11
Query 'Per CDM, re-query: If the vitals were not assessed, then please answer with "No" to the question in this field. Thank you. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 20:35:11
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 20:35:05
User opened query 'Per CDM, re-query: If the vitals were not assessed, then please answer with "No" to the question in this field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:09:05
User closed query 'Per CDM: Please note that a Yes or No is required for "Were vital signs assessed?" and the field should not remain empty. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:09:05
Query 'Per CDM: Please note that a Yes or No is required for "Were vital signs assessed?" and the field should not remain empty. ' answered with 'Subject did not get post dose vitals due to not getting vaccination ' (Site from DM).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 21:12:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 15:13:24
User opened query 'Per CDM: Please note that a Yes or No is required for "Were vital signs assessed?" and the field should not remain empty. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 15:13:22
Query 'Data is required. Please complete.' answered with 'subject did not have post vitals done pi withdrew ip ' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 22:24:20
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 22:23:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 22:23:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 22:22:25

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Nov 2020 22:23:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 22:23:54
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Nov 2020 22:22:25
User entered '27 Jul 2020'	(b) (4), (b) (6)	12 Nov 2020 22:22:25



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	(b) (4) System	12 Nov 2020 22:23:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 22:23:54
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	12 Nov 2020 22:22:25
User entered '19:58'	(b) (4), (b) (6)	12 Nov 2020 22:22:25

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered empty.	System	12 Nov 2020 22:23:54
User entered '27 Jul 2020 19:58'	System	12 Nov 2020 22:22:25

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty; reason for change Data Entry Error	(b) (4)	12 Nov 2020 22:23:54
User entered '36.2' C	(b) (4), (b) (6)	12 Nov 2020 22:22:25

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty; reason for change Data Entry Error	(b) (4)	12 Nov 2020 22:23:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Nov 2020 22:22:25

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:22:25

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty; reason for change Data Entry Error	(b) (4)	12 Nov 2020 22:23:54
User entered '74'	(b) (4), (b) (6)	12 Nov 2020 22:22:25

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered empty.	System	12 Nov 2020 22:23:54
User entered 'bpm'	System	12 Nov 2020 22:22:25

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty; reason for change Data Entry Error	(b) (4)	12 Nov 2020 22:23:54
User entered '16'	(b) (4), (b) (6)	12 Nov 2020 22:22:25



US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered empty.	System	12 Nov 2020 22:23:54
User entered 'breaths/min'	System	12 Nov 2020 22:22:25

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty; reason for change Data Entry Error	(b) (4)	12 Nov 2020 22:23:54
User entered '128'	(b) (4), (b) (6)	12 Nov 2020 22:22:25

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered empty.	System	12 Nov 2020 22:23:54
User entered 'mmHg'	System	12 Nov 2020 22:22:25

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty; reason for change Data Entry Error	(b) (4)	12 Nov 2020 22:23:54
User entered '72'	(b) (4), (b) (6)	12 Nov 2020 22:22:25

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered empty.	System	12 Nov 2020 22:23:54
User entered 'mmHg'	System	12 Nov 2020 22:22:25

US3022031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:30:49

US3022031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:30:49

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:31:40



US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:31:40

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

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 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'DUE TO OVERDOSE OF MED'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:31:40

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered empty.	System	11 Nov 2020 16:31:40

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:31:40

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:31:40

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered empty.	System	11 Nov 2020 16:31:40

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:31:40

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered empty.	System	11 Nov 2020 16:31:40



US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered empty.	System	11 Nov 2020 16:31:40

US3022031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:32:01

US3022031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:32:01

US3022031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '14:09'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:32:01

US3022031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '29 Sep 2020 14:09'	System	11 Nov 2020 16:32:01

US3022031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:49:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 29SEP2020 is reported under Visit 2 Day 29 visit in EDC. However the same is missing in PPD Central lab. Please confirm and update the correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:32:49
Query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 29SEP2020 is reported under Visit 2 Day 29 visit in EDC. However the same is missing in PPD Central lab. Please confirm and update the correct date to update in GCL records.' answered with 'accession number: 1F637765306' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 20:34:27
User opened query 'Per GCL Lab Reconciliation: Central Laboratory - Nasopharyngeal Swab: Sample Collection Date 29SEP2020 is reported under Visit 2 Day 29 visit in EDC. However the same is missing in PPD Central lab. Please confirm and update the correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:00:03
User entered '29 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 16:32:13

US3022031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Nov 2020 16:32:13

US3022031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:32:13



US3022031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '13:58'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:32:13

**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:49:51**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '29 Sep 2020 13:58'	System	11 Nov 2020 16:32:13

US3022031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Nov 2020 16:32:13

US3022031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:32:13

US3022031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:32:13

US3022031

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered empty.	System	11 Nov 2020 16:32:13

US3022031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:32:30

US3022031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '1'	System	11 Nov 2020 16:32:30



US3022031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	13 Nov 2020 21:31:33
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	11 Nov 2020 16:34:08
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:34:08

US3022031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:34:08

US3022031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 21:31:33
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	11 Nov 2020 16:34:08

US3022031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty; reason for change Data Entry Error	(b) (4)	
	Shanice Bennett (b) (4)	13 Nov 2020 21:31:33
User entered 'SUBJECT NOT CALLED DUE TO NOT RECIEVING VAX 2'	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 16:34:08

US3022031

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:59:32

US3022031

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'I'	System	11 Nov 2020 16:59:32

US3022031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	13 Nov 2020 21:31:51
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	11 Nov 2020 16:59:44
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:59:44

US3022031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:59:44



US3022031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 21:31:51
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	11 Nov 2020 16:59:44

US3022031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty; reason for change Data Entry Error	(b) (4)	13 Nov 2020 21:31:51
User entered 'CONTACT NOT MADE'	Shanice Bennett (b) (4)	11 Nov 2020 16:59:44
	(b) (4), (b) (6)	

US3022031

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 16:59:49

US3022031

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'I'	System	11 Nov 2020 16:59:49

US3022031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	13 Nov 2020 21:32:07
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	11 Nov 2020 17:00:03
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 17:00:03

US3022031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:00:03

US3022031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 21:32:07
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	11 Nov 2020 17:00:03

US3022031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty; reason for change Data Entry Error	(b) (4)	13 Nov 2020 21:32:07
User entered 'CONTACT NOT MADE'	Shanice Bennett (b) (4)	11 Nov 2020 17:00:03
	(b) (4)	
	(b) (4), (b) (6)	



US3022031

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:00:07

US3022031

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered 'I'	System	11 Nov 2020 17:00:07

US3022031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:00:18

US3022031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 20:37:59
User entered '28 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 17:00:18

US3022031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[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 19:23:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:00:18

US3022031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User entered 'VISIT3'	System	11 Nov 2020 17:00:18

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Nov 2020 20:38:09
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	24 Nov 2020 20:38:09
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:38:09
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Nov 2020 20:37:59
User entered '28 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 17:00:43



US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '14:00'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User entered '28 Oct 2020 14:00'	System	24 Nov 2020 20:38:09
User entered '28 Sep 2020 14:00'	System	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '76'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User entered 'bpm'	System	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '14'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:00:43



US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User entered 'breaths/min'	System	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '117'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User entered 'mmHg'	System	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '70'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19
User entered 'mmHg'	System	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:19

US3022031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:00:52



US3022031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Nov 2020 20:38:16
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:38:16
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Nov 2020 20:37:59
User entered '28 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 17:00:52

US3022031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Sample dated 28SEP2020 is recorded under Visit 3 Day 57 visit in EDC, however 29sep2020 is reported under Visit 2 Day 29 visit which is after the date of visit 3. Sample dated 28OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab. Hence please correct the date on this page for the Visit 3 DAY 57.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 08:36:25
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Sample dated 28SEP2020 is recorded under Visit 3 Day 57 visit in EDC, however 29sep2020 is reported under Visit 2 Day 29 visit which is after the date of visit 3. Sample dated 28OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab. Hence please correct the date on this page for the Visit 3 DAY 57.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:38:38
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Sample dated 28SEP2020 is recorded under Visit 3 Day 57 visit in EDC, however 29sep2020 is reported under Visit 2 Day 29 visit which is after the date of visit 3. Sample dated 28OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab. Hence please correct the date on this page for the Visit 3 DAY 57.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:19:08
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28SEP2020 is recorded under Visit 3 Day 57 visit in EDC, however 28OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab. Please confirm the correct date and update EDC or PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:12:52

US3022031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28SEP2020 is recorded under Visit 3 Day 57 visit in EDC, however 28OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab. Please confirm the correct date and update EDC or PPD Central lab.' answered with '28sep2020 date is correct for visit 3' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 21:45:35
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28SEP2020 is recorded under Visit 3 Day 57 visit in EDC, however 28OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab. Please confirm the correct date and update EDC or PPD Central lab.' (Site from DM).	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 05:27:48
	(b) (4), (b) (6)	11 Nov 2020 17:01:11

US3022031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Nov 2020 20:38:26
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		24 Nov 2020 20:38:26
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:38:26
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	24 Nov 2020 20:37:59
User entered '28 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 17:01:11

US3022031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '14:24'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:01:11

US3022031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '28 Oct 2020 14:24'	System	24 Nov 2020 20:38:26
User entered '28 Sep 2020 14:24'	System	11 Nov 2020 17:01:11

US3022031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:01:15

US3022031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '1'	System	11 Nov 2020 17:01:15



US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 64'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-09-27T18:01:29', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'a100c1b9-0929-4564-8c51-347e55d644f5'	System	27 Sep 2020 22:02:58
User entered 'No (N)'	System	27 Sep 2020 22:02:58

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-09-27T18:02:34', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'a100c1b9-0929-4564-8c51-347e55d644f5'	System	27 Sep 2020 22:02:58
User entered 'No (N)'	System	27 Sep 2020 22:02:58

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-09-27T18:02:56', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'a100c1b9-0929-4564-8c51-347e55d644f5'	System	27 Sep 2020 22:02:58
User entered '27 Sep 2020 18:02:56'	System	27 Sep 2020 22:02:58

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered '26 Sep 2020 00:01'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered '30 Sep 2020 23:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 71'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-10-03T19:46:25', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '0b2b558a-23fc-44db-952c-b6171128978a'	System	03 Oct 2020 23:46:59
User entered 'No (N)'	System	03 Oct 2020 23:46:59



US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-10-03T19:46:43', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '0b2b558a-23fc-44db-952c-b6171128978a'	System	03 Oct 2020 23:46:59
User entered 'No (N)'	System	03 Oct 2020 23:46:59

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-10-03T19:46:54', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '0b2b558a-23fc-44db-952c-b6171128978a' User entered '03 Oct 2020 19:46:54'	System	03 Oct 2020 23:46:59
	System	03 Oct 2020 23:46:59

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered '03 Oct 2020 00:01'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered '07 Oct 2020 23:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 78'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-10-10T14:35:15', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '83e614f1-dc8f-4189-9adc-e18e2bb58457'	System	10 Oct 2020 18:35:53
User entered 'Yes (Y)'	System	10 Oct 2020 18:35:53

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-10-10T14:35:26', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '83e614f1-dc8f-4189-9adc-e18e2bb58457'	System	10 Oct 2020 18:35:53
User entered 'No (N)'	System	10 Oct 2020 18:35:53

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-10-10T14:35:33', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '83e614f1-dc8f-4189-9adc-e18e2bb58457'	System	10 Oct 2020 18:35:53
User entered 'No (N)'	System	10 Oct 2020 18:35:53



US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-10-10T14:35:42', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '83e614f1-dc8f-4189-9adc-e18e2bb58457'	System	10 Oct 2020 18:35:53
User entered 'No (N)'	System	10 Oct 2020 18:35:53

**US3022031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-10-10T14:35:50', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '83e614f1-dc8f-4189-9adc-e18e2bb58457'	System	10 Oct 2020 18:35:53
User entered '10 Oct 2020 14:35:50'	System	10 Oct 2020 18:35:53

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered '10 Oct 2020 00:01'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered '14 Oct 2020 23:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 92'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-10-26T07:47:02', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '34b90a57-d45a-4e23-b055-8802f7b09cde'	System	26 Oct 2020 11:47:10
User entered 'No (N)'	System	26 Oct 2020 11:47:10

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-10-26T07:46:48', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '34b90a57-d45a-4e23-b055-8802f7b09cde'	System	26 Oct 2020 11:47:10
User entered 'No (N)'	System	26 Oct 2020 11:47:10

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-10-26T07:47:07', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '34b90a57-d45a-4e23-b055-8802f7b09cde' User entered '26 Oct 2020 07:47:07'	System	26 Oct 2020 11:47:10
	System	26 Oct 2020 11:47:10



US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered '24 Oct 2020 00:01'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered '28 Oct 2020 23:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 99'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-10-31T17:23:48', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '6b743986-4ee3-4ee9-a35f-b90238d9d4d9'	System	31 Oct 2020 21:24:05
User entered 'No (N)'	System	31 Oct 2020 21:24:05

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-10-31T17:23:55', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '6b743986-4ee3-4ee9-a35f-b90238d9d4d9'	System	31 Oct 2020 21:24:05
User entered 'No (N)'	System	31 Oct 2020 21:24:05

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-10-31T17:24:01', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '6b743986-4ee3-4ee9-a35f-b90238d9d4d9'	System	31 Oct 2020 21:24:05
User entered '31 Oct 2020 17:24:01'	System	31 Oct 2020 21:24:05

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered '31 Oct 2020 00:01'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:59
Data entry locked.	System	27 Jul 2020 23:43:52
User entered '04 Nov 2020 23:59'	System	27 Jul 2020 23:43:52



US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 106'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

Please 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)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21



US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21



US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

Please 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)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

Please 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)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21
Data entry locked.	System	27 Jul 2020 23:43:52
User entered '07 Nov 2020 00:01'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21
Data entry locked.	System	27 Jul 2020 23:43:52
User entered '11 Nov 2020 23:59'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21
Data entry locked.	System	27 Jul 2020 23:43:52
User entered 'Day 113'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

Please 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)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21



US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21



US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21



US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Please 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)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Please 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)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21
Data entry locked.	System	27 Jul 2020 23:43:52
User entered '14 Nov 2020 00:01'	System	27 Jul 2020 23:43:52

US3022031

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:15:21
Data entry locked.	System	27 Jul 2020 23:43:52
User entered '18 Nov 2020 23:59'	System	27 Jul 2020 23:43:52



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[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 (9e3e3d2ca72f6e47)', Time: '2020-11-27T21:55:17', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '0651e2a5-c310-41e7-811b-67d398d9bbf5'	System	28 Nov 2020 02:55:45
User entered 'No (N)'	System	28 Nov 2020 02:55:45

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

Have you been exposed to someone with 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 (9e3e3d2ca72f6e47)', Time: '2020-11-27T21:55:30', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '0651e2a5-c310-41e7-811b-67d398d9bbf5'	System	28 Nov 2020 02:55:45
User entered 'No (N)'	System	28 Nov 2020 02:55:45

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-11-27T21:55:41', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '0651e2a5-c310-41e7-811b-67d398d9bbf5'	System	28 Nov 2020 02:55:45
User entered '27 Nov 2020 21:55:41'	System	28 Nov 2020 02:55:45

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (9e3e3d2ca72f6e47)', Time: '2020-12-06T13:46:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'ea3c1ece-9df0-4e6d-8fa3-5ffc8f6251a5'	System	06 Dec 2020 18:49:06
User entered 'No (N)'	System	06 Dec 2020 18:49:06

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (9e3e3d2ca72f6e47)', Time: '2020-12-06T13:46:03', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'ea3c1ece-9df0-4e6d-8fa3-5ffc8f6251a5'	System	06 Dec 2020 18:49:06
User entered 'No (N)'	System	06 Dec 2020 18:49:06

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9e3e3d2ca72f6e47)', Time: '2020-12-06T13:46:07', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'ea3c1ece-9df0-4e6d-8fa3-5ffc8f6251a5'	System	06 Dec 2020 18:49:06
User entered '06 Dec 2020 13:46:07'	System	06 Dec 2020 18:49:06

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2020-12-17T09:52:24', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '3e80ce1d-5436-4220-a4cc-81d88f60adbb' User entered 'No (N)'	System	17 Dec 2020 14:52:39
	System	17 Dec 2020 14:52:39

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2020-12-17T09:52:31', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '3e80ce1d-5436-4220-a4cc-81d88f60adbb'	System	17 Dec 2020 14:52:39
User entered 'No (N)'	System	17 Dec 2020 14:52:39

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2020-12-17T09:52:37', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '3e80ce1d-5436-4220-a4cc-81d88f60adbb' User entered '17 Dec 2020 09:52:37'	System	17 Dec 2020 14:52:39
	System	17 Dec 2020 14:52:39

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2020-12-23T09:51:09', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'aa9fa9a7-e0a6-4b0e-9528-ed404b8630b6'	System	23 Dec 2020 14:51:28
User entered 'No (N)'	System	23 Dec 2020 14:51:28

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2020-12-23T09:51:15', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'aa9fa9a7-e0a6-4b0e-9528-ed404b8630b6'	System	23 Dec 2020 14:51:28
User entered 'No (N)'	System	23 Dec 2020 14:51:28

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2020-12-23T09:51:24', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'aa9fa9a7-e0a6-4b0e-9528-ed404b8630b6' User entered '23 Dec 2020 09:51:24'	System	23 Dec 2020 14:51:28
	System	23 Dec 2020 14:51:28

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2020-12-30T00:02:01', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'ac945ae8-b5c3-4f5c-89fc-0ce4435ace02'	System	30 Dec 2020 05:02:15
User entered 'No (N)'	System	30 Dec 2020 05:02:15



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2020-12-30T00:02:06', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'ac945ae8-b5c3-4f5c-89fc-0ce4435ace02'	System	30 Dec 2020 05:02:15
User entered 'No (N)'	System	30 Dec 2020 05:02:15

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2020-12-30T00:02:11', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'ac945ae8-b5c3-4f5c-89fc-0ce4435ace02'	System	30 Dec 2020 05:02:15
User entered '30 Dec 2020 00:02:11'	System	30 Dec 2020 05:02:15

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-01-06T00:02:40', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'ef96a169-2259-4776-b2a3-13c019d7f83b'	System	06 Jan 2021 05:03:12
User entered 'No (N)'	System	06 Jan 2021 05:03:12

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-01-06T00:02:45', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'ef96a169-2259-4776-b2a3-13c019d7f83b'	System	06 Jan 2021 05:03:12
User entered 'No (N)'	System	06 Jan 2021 05:03:12

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-01-06T00:02:55', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'ef96a169-2259-4776-b2a3-13c019d7f83b' User entered '06 Jan 2021 00:02:55'	System	06 Jan 2021 05:03:12
	System	06 Jan 2021 05:03:12



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-01-13T03:48:46', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '4a2d1f8b-494f-4078-901c-fbf781802624'	System	13 Jan 2021 08:49:10
User entered 'No (N)'	System	13 Jan 2021 08:49:10

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-01-13T03:49:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '4a2d1f8b-494f-4078-901c-fbf781802624'	System	13 Jan 2021 08:49:10
User entered 'No (N)'	System	13 Jan 2021 08:49:10

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-01-13T03:49:05', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '4a2d1f8b-494f-4078-901c-fbf781802624' User entered '13 Jan 2021 03:49:05'	System	13 Jan 2021 08:49:10
	System	13 Jan 2021 08:49:10

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-01-20T06:56:31', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '78792496-9bea-49b1-825d-6a1192a77fdb'	System	20 Jan 2021 11:57:00
User entered 'No (N)'	System	20 Jan 2021 11:57:00

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-01-20T06:56:34', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '78792496-9bea-49b1-825d-6a1192a77fdb'	System	20 Jan 2021 11:57:00
User entered 'No (N)'	System	20 Jan 2021 11:57:00

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-01-20T06:56:54', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '78792496-9bea-49b1-825d-6a1192a77fdb' User entered '20 Jan 2021 06:56:54'	System	20 Jan 2021 11:57:00
	System	20 Jan 2021 11:57:00

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-01-29T17:11:48', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '03a2f79f-241a-45c5-9fa4-8d8dc579defc'	System	03 Feb 2021 05:02:12
User entered 'No (N)'	System	03 Feb 2021 05:02:12



US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-01-29T17:11:52', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '03a2f79f-241a-45c5-9fa4-8d8dc579defc' User entered 'No (N)'	System	03 Feb 2021 05:02:12
	System	03 Feb 2021 05:02:12

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-01-29T17:11:56', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '03a2f79f-241a-45c5-9fa4-8d8dc579defc' User entered '29 Jan 2021 17:11:56'	System	03 Feb 2021 05:02:12
	System	03 Feb 2021 05:02:12

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-02-03T00:01:41', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c36bd317-b4d2-4ac9-b506-291025a3cab5'	System	03 Feb 2021 05:02:31
User entered 'No (N)'	System	03 Feb 2021 05:02:31

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-02-03T00:01:47', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c36bd317-b4d2-4ac9-b506-291025a3cab5'	System	03 Feb 2021 05:02:31
User entered 'No (N)'	System	03 Feb 2021 05:02:31

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-02-03T00:01:52', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'c36bd317-b4d2-4ac9-b506-291025a3cab5'	System	03 Feb 2021 05:02:31
User entered '03 Feb 2021 00:01:52'	System	03 Feb 2021 05:02:31



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-02-10T00:01:25', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '2453ab95-9c42-404d-91e4-087323e56b6e'	System	10 Feb 2021 05:03:58
User entered 'No (N)'	System	10 Feb 2021 05:03:58

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-02-10T00:01:41', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '2453ab95-9c42-404d-91e4-087323e56b6e'	System	10 Feb 2021 05:03:58
User entered 'No (N)'	System	10 Feb 2021 05:03:58

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-02-10T00:02:21', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '2453ab95-9c42-404d-91e4-087323e56b6e' User entered '10 Feb 2021 00:02:21'	System	10 Feb 2021 05:03:58
	System	10 Feb 2021 05:03:58

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-02-17T00:01:48', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '8aca0209-2f03-4e0c-ab68-6ec7629a4763' User entered 'No (N)'	System	17 Feb 2021 05:03:53
	System	17 Feb 2021 05:03:53

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-02-17T00:01:53', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '8aca0209-2f03-4e0c-ab68-6ec7629a4763' User entered 'No (N)'	System	17 Feb 2021 05:03:53
	System	17 Feb 2021 05:03:53

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-02-17T00:01:57', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '8aca0209-2f03-4e0c-ab68-6ec7629a4763' User entered '17 Feb 2021 00:01:57'	System	17 Feb 2021 05:03:53
	System	17 Feb 2021 05:03:53

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-02-24T00:01:49', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '99ee8a2d-97d8-4e02-910b-adc46958eca8' User entered 'No (N)'	System	24 Feb 2021 05:03:48
	System	24 Feb 2021 05:03:48



US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-02-24T00:02:01', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '99ee8a2d-97d8-4e02-910b-adc46958eca8'	System	24 Feb 2021 05:03:48
User entered 'No (N)'	System	24 Feb 2021 05:03:48

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-02-24T00:02:06', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '99ee8a2d-97d8-4e02-910b-adc46958eca8' User entered '24 Feb 2021 00:02:06'	System	24 Feb 2021 05:03:48
	System	24 Feb 2021 05:03:48

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-03-06T11:04:34-05:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '70f8dbeb-287f-47e2-ad25-7a5920bc65b7'	System	06 Mar 2021 16:04:48
User entered 'No (N)'	System	06 Mar 2021 16:04:48

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-03-06T11:04:38-05:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '70f8dbeb-287f-47e2-ad25-7a5920bc65b7'	System	06 Mar 2021 16:04:48
User entered 'No (N)'	System	06 Mar 2021 16:04:48

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-03-06T11:04:45-05:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '70f8dbeb-287f-47e2-ad25-7a5920bc65b7'	System	06 Mar 2021 16:04:48
User entered '06 Mar 2021 11:04:45'	System	06 Mar 2021 16:04:48



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-03-12T11:30:32-05:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '9871d7e6-61ba-43d0-be00-54d9a10f8267'	System	12 Mar 2021 16:30:57
User entered 'No (N)'	System	12 Mar 2021 16:30:57

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-03-12T11:30:37-05:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '9871d7e6-61ba-43d0-be00-54d9a10f8267'	System	12 Mar 2021 16:30:57
User entered 'No (N)'	System	12 Mar 2021 16:30:57

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-03-12T11:30:54-05:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '9871d7e6-61ba-43d0-be00-54d9a10f8267'	System	12 Mar 2021 16:30:57
User entered '12 Mar 2021 11:30:54'	System	12 Mar 2021 16:30:57

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-03-20T20:50:34-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '08ea1a2e-7a1f-4f65-b5fe-f9456faf8b7c'	System	21 Mar 2021 00:51:04
User entered 'No (N)'	System	21 Mar 2021 00:51:04

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-03-20T20:50:43-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '08ea1a2e-7a1f-4f65-b5fe-f9456faf8b7c'	System	21 Mar 2021 00:51:04
User entered 'No (N)'	System	21 Mar 2021 00:51:04

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-03-20T20:50:59-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '08ea1a2e-7a1f-4f65-b5fe-f9456faf8b7c'	System	21 Mar 2021 00:51:04
User entered '20 Mar 2021 20:50:59'	System	21 Mar 2021 00:51:04

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-03-24T00:02:28-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'a7d1783a-a94c-4b2c-879b-0e64cd5b8de6'	System	24 Mar 2021 04:03:38
User entered 'No (N)'	System	24 Mar 2021 04:03:38



US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-03-24T00:02:32-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'a7d1783a-a94c-4b2c-879b-0e64cd5b8de6'	System	24 Mar 2021 04:03:38
User entered 'No (N)'	System	24 Mar 2021 04:03:38

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-03-24T00:02:39-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'a7d1783a-a94c-4b2c-879b-0e64cd5b8de6' User entered '24 Mar 2021 00:02:39'	System	24 Mar 2021 04:03:38
	System	24 Mar 2021 04:03:38

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-02T04:48:52-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '0505887e-fbd4-438f-9166-016552c6255d' User entered 'No (N)'	System	02 Apr 2021 08:49:06
	System	02 Apr 2021 08:49:06

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-02T04:48:55-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '0505887e-fbd4-438f-9166-016552c6255d'	System	02 Apr 2021 08:49:06
User entered 'No (N)'	System	02 Apr 2021 08:49:06

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-02T04:48:59-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '0505887e-fbd4-438f-9166-016552c6255d'	System	02 Apr 2021 08:49:06
User entered '02 Apr 2021 04:48:59'	System	02 Apr 2021 08:49:06



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-09T13:36:28-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'dfafac2e-26fe-440b-a037-b35f20f0e022'	System	09 Apr 2021 17:36:40
User entered 'No (N)'	System	09 Apr 2021 17:36:40

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-09T13:36:32-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'dfafac2e-26fe-440b-a037-b35f20f0e022'	System	09 Apr 2021 17:36:40
User entered 'No (N)'	System	09 Apr 2021 17:36:40

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-09T13:36:36-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'dfafac2e-26fe-440b-a037-b35f20f0e022'	System	09 Apr 2021 17:36:40
User entered '09 Apr 2021 13:36:36'	System	09 Apr 2021 17:36:40

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-14T18:52:28-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '15778b30-7a5e-4858-bb39-6108f3d5d2a5'	System	14 Apr 2021 22:52:47
User entered 'No (N)'	System	14 Apr 2021 22:52:47

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-14T18:52:33-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '15778b30-7a5e-4858-bb39-6108f3d5d2a5'	System	14 Apr 2021 22:52:47
User entered 'No (N)'	System	14 Apr 2021 22:52:47

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-14T18:52:38-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '15778b30-7a5e-4858-bb39-6108f3d5d2a5'	System	14 Apr 2021 22:52:47
User entered '14 Apr 2021 18:52:38'	System	14 Apr 2021 22:52:47

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-21T13:31:59-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'a06715cd-de87-4b8a-846b-356fb331142e'	System	21 Apr 2021 17:32:15
User entered 'No (N)'	System	21 Apr 2021 17:32:15



US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-21T13:32:04-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'a06715cd-de87-4b8a-846b-356fb331142e'	System	21 Apr 2021 17:32:15
User entered 'No (N)'	System	21 Apr 2021 17:32:15

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-21T13:32:12-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: 'a06715cd-de87-4b8a-846b-356fb331142e'	System	21 Apr 2021 17:32:15
User entered '21 Apr 2021 13:32:12'	System	21 Apr 2021 17:32:15

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-28T02:01:43-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '36d78b1a-bf29-42ca-b85f-ce18d053b35a'	System	28 Apr 2021 22:58:17
User entered 'No (N)'	System	28 Apr 2021 22:58:17

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

Have you been exposed to someone with 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 (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-28T02:02:02-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '36d78b1a-bf29-42ca-b85f-ce18d053b35a'	System	28 Apr 2021 22:58:17
User entered 'No (N)'	System	28 Apr 2021 22:58:17

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-04-28T02:02:21-04:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '36d78b1a-bf29-42ca-b85f-ce18d053b35a'	System	28 Apr 2021 22:58:17
User entered '28 Apr 2021 02:02:21'	System	28 Apr 2021 22:58:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 02:15:21

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 02:15:21



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 02:15:21



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 02:15:21

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 02:15:21



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 02:15:21



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 02:15:21



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:15:21



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:15:21



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:15:21

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:15:21



**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 02:15:21

**US3022031**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:49:51**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 02:15:21



US3022031

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:49:51

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-02-28T13:52:44-05:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '9057222d-6930-4046-9f99-0c137832e8e0'	System	28 Feb 2021 18:52:59
User entered 'No (N)'	System	28 Feb 2021 18:52:59

US3022031

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:49:51

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:31:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D0DDFD23-F1EF-40BA-A91C-12C28B75999C)', Time: '2021-02-28T13:52:55-05:00', User OID: 'PatientReportedOutcome (US3022031)', ODM File OID: '9057222d-6930-4046-9f99-0c137832e8e0' User entered '28 Feb 2021 13:52:55'	System	28 Feb 2021 18:52:59
	System	28 Feb 2021 18:52:59

US3022031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 19:47:54

US3022031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 19:47:54

US3022031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 19:47:54

US3022031

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 19:47:54

US3022031

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 19:47:57

US3022031

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:23:09
User entered '1'	System	28 Dec 2020 19:47:57



US3022031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 19:48:09

US3022031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 19:48:09

US3022031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 19:48:09

US3022031

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 19:48:09

US3022031

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 19:48:15

US3022031

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User entered 'I'	System	28 Dec 2020 19:48:15

US3022031

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:48:28

US3022031

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:48:28



US3022031

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:48:28

US3022031

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:48:28

US3022031

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:48:34

US3022031

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User entered '1'	System	25 Jan 2021 21:48:34

US3022031

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:54:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:07:33

US3022031

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:54:26
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:07:33

US3022031

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:54:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:07:33

US3022031

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:54:26
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:07:33



US3022031

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:54:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:07:38

US3022031

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:52:16
User entered '1'	System	25 Feb 2021 22:07:38

US3022031

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:55:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:06:36

US3022031

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:55:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:06:36

US3022031

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:55:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:06:36

US3022031

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:55:44
User entered 'VISIT4'	System	17 Mar 2021 20:06:36

US3022031

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:55:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:07:13

US3022031

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:55:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:07:13



US3022031

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:55:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:07:36

US3022031

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:55:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered '17 Mar 2021'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:07:36

US3022031

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:55:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered '13:20'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:07:36

**US3022031**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:49:51**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:55:44
User entered '17 Mar 2021 13:20'	System	17 Mar 2021 20:07:36

US3022031

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:55:44
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 20:07:51

US3022031

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:55:44
User entered '1'	System	17 Mar 2021 20:07:51

US3022031

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:51
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:53:13

US3022031

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:51
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered '22 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:53:13



US3022031

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:51
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:53:13

US3022031

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:51
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:53:13

US3022031

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:51
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:53:17

US3022031

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:14:51
User entered 'I'	System	24 Mar 2021 15:53:17

US3022031

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

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 22:00:16

US3022031

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

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 22:00:16

US3022031

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

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[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 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 22:00:16

US3022031

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

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 22:00:16



**US3022031**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:49:51**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 22:00:52

**US3022031**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:49:51**

[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 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:38:06

US3022031

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:51

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 22:00:52

US3022031

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:51

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:10:55
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4)	
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:09:05
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:17:09
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 12:16:55
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 12:16:55
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:01:40
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:00:05
User entered empty. WR# 5295537	(b) (4)	System
Amendment Manager inserted this DataPoint.	System	10 Mar 2021 16:55:28
		06 Mar 2021 10:38:06

US3022031

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:51

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 22:00:52

US3022031

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:51

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 22:00:52

**US3022031**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:49:51**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 11:04:22
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	13 Jan 2021 22:00:52

US3022031

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:51

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Not Administered (NA)' reason for change: Data Entry Error	(b) (4)	10 Feb 2021 13:36:24
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	10 Feb 2021 13:36:24
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 11:04:22
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	13 Jan 2021 22:00:52



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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:51

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:36:24
User closed query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	System	13 Jan 2021 22:01:03
Query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' answered by data change (Site from System).	System	13 Jan 2021 22:01:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 22:01:03
User opened query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	System	13 Jan 2021 22:00:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 22:00:52

US3022031

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:51

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered empty.	System	13 Jan 2021 22:00:52

US3022031

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:51

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered '1'	System	10 Feb 2021 13:36:24
User entered empty.	System	13 Jan 2021 22:00:52

US3022031

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered empty.	System	10 Feb 2021 13:37:58
DataPoint set to visible.	System	10 Feb 2021 13:36:24

US3022031

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58



US3022031

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered empty.	System	10 Feb 2021 13:37:58
DataPoint set to visible.	System	10 Feb 2021 13:36:24

US3022031

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '13:50'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered '13 Jan 2021 13:50'	System	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '37.2' C	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58



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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

**US3022031**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:49:51**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '80'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered 'bpm'	System	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered 'breaths/min'	System	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '124'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered 'mmHg'	System	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '75'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58



US3022031

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered 'mmHg'	System	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered empty.	System	10 Feb 2021 13:37:58
DataPoint set to visible.	System	10 Feb 2021 13:36:24

US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '16:00'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58



US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered '13 Jan 2021 16:00'	System	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

**US3022031**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:49:51**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '70'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered 'bpm'	System	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '15'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered 'breaths/min'	System	10 Feb 2021 13:37:58



US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '139'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered 'mmHg'	System	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '78'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:37:58

US3022031

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered 'mmHg'	System	10 Feb 2021 13:37:58

US3022031

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:38:12

US3022031

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:38:12

US3022031

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:38:27

US3022031

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:38:27



US3022031

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:38:27

US3022031

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered 'mRNA-1273'	System	10 Feb 2021 13:38:27
DataPoint set to visible.	System	10 Feb 2021 13:36:24

US3022031

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	10 Feb 2021 13:41:38
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	10 Feb 2021 13:41:38
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 13:41:38
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	10 Feb 2021 13:38:27
User entered '09 Feb 2021'	(b) (4), (b) (6)	10 Feb 2021 13:38:27

US3022031

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '15:30'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:38:27

US3022031

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered '13 Jan 2021 15:30'	System	10 Feb 2021 13:41:38
User entered '09 Feb 2021 15:30'	System	10 Feb 2021 13:38:27

US3022031

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:38:27

US3022031

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered 'ONCE'	System	10 Feb 2021 13:38:27

US3022031

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered 'INTRAMUSCULAR'	System	10 Feb 2021 13:38:27



US3022031

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 22:01:27

US3022031

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 22:01:27

US3022031

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '13:15'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 22:01:27

US3022031

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered '13 Jan 2021 13:15'	System	13 Jan 2021 22:01:27

US3022031

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:49:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 22:01:44

US3022031

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:49:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 22:01:44

US3022031

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:49:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '13:26'	(b) (4) (b) (4), (b) (6)	13 Jan 2021 22:01:44

US3022031

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:49:51

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered '13 Jan 2021 13:26'	System	13 Jan 2021 22:01:44



US3022031

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

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:38:33

US3022031

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

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:44:16
User entered '1'	System	10 Feb 2021 13:38:33

US3022031

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:28:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:00

US3022031

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:28:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:00

US3022031

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:28:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:00

US3022031

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:51

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:28:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:00

US3022031

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:28:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:06

US3022031

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:28:42
User entered '1'	System	10 Feb 2021 13:39:06



US3022031

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:51

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:28:42
User entered '1'	System	10 Feb 2021 13:39:06
DataPoint set to visible.	System	10 Feb 2021 13:39:06

US3022031

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:24

US3022031

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:24

US3022031

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:24

US3022031

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User entered 'OLD29'	System	10 Feb 2021 13:39:24

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:53

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:53

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '15:02'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:53



US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User entered '09 Feb 2021 15:02'	System	10 Feb 2021 13:39:53

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:53

**US3022031**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:49:51**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:53

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:53

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '72'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:53

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User entered 'bpm'	System	10 Feb 2021 13:39:53

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:53

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User entered 'breaths/min'	System	10 Feb 2021 13:39:53



US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '136'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:53

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User entered 'mmHg'	System	10 Feb 2021 13:39:53

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '74'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:39:53

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User entered 'mmHg'	System	10 Feb 2021 13:39:53

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10

US3022031

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:51

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10

US3022031

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:40:00

US3022031

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:40:00



US3022031

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:40:23

US3022031

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '09 Feb 2021'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:40:23

US3022031

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '16:21'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 13:40:23

US3022031

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:51

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:40:10
User entered '09 Feb 2021 16:21'	System	10 Feb 2021 13:40:23

US3022031

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:49:51

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:22
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:35:10
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:55:21

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:34
User entered 'USA-US051-2020-mRNA-1273-P301000001'	System	26 Aug 2020 11:50:48
User entered 'New'	(b) (4), (b) (6)	26 Aug 2020 11:50:48

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Overdoses and underdoses NEC, HLT: Overdoses NEC, PT: Overdose, LLT: Drug overdose - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 00:50:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 00:50:25
Data point term sent to Coder	System	30 Sep 2020 20:20:54
User entered 'Overdose of Klonopin' reason for change: Data Entry Error	Shanice Bennett (b) (4)	30 Sep 2020 20:20:39
Data point term sent to Coder	System	30 Sep 2020 19:46:37
Coding entries removed.	Shanice Bennett (b) (4)	30 Sep 2020 19:46:19
User entered 'overdose of benzodiazepine' reason for change: Data Entry Error	Shanice Bennett (b) (4)	30 Sep 2020 19:46:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Myopathies, PT: Rhabdomyolysis, LLT: Rhabdomyolysis - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 18:58:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Aug 2020 18:58:43
Data point term sent to Coder	System	25 Aug 2020 18:57:39
User entered 'Rhabdomyolysis'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11



US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:55:58
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	30 Sep 2020 19:44:31
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	30 Sep 2020 19:44:21
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:18:13
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '10 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:49:51**

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:57:11

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US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '19 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11



US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:57:11

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US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User closed query 'Per ETRTR: Please confirm the event severity of grade 4. Was this event considered life-threatening? If no, please consider updating event to grade 3' (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:37:20
Query 'Per ETRTR: Please confirm the event severity of grade 4. Was this event considered life-threatening? If no, please consider updating event to grade 3' answered with 'SAE/patient went to hospital - so grade 4 is correct' (Site from CRA).	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 12:59:25
User opened query 'Per ETRTR: Please confirm the event severity of grade 4. Was this event considered life-threatening? If no, please consider updating event to grade 3' (Site from CRA).	(b) (4), (b) (6)	27 Aug 2020 20:57:58
User entered 'Grade 4 (Grade 4)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Aug 2020 18:58:32
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Aug 2020 18:57:11
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	25 Aug 2020 18:58:53
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	25 Aug 2020 18:58:53
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	25 Aug 2020 18:58:32
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	25 Aug 2020 18:58:32
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '10 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	25 Aug 2020 18:58:32
User entered empty.	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '19 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	25 Aug 2020 18:58:32
User entered empty.	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11



US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:58:53
User entered empty.	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	26 Aug 2020 12:39:41
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	26 Aug 2020 12:39:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 12:39:09
User entered 'Related (RELATED)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User closed query 'PV Query: Please confirm the action taken with the study drug in response to the event. Was it delayed or withdrawn? Please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:48:33
Query 'PV Query: Please confirm the action taken with the study drug in response to the event. Was it delayed or withdrawn? Please update the EDC accordingly.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:04:28
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 13:04:19
User opened query 'PV Query: Please confirm the action taken with the study drug in response to the event. Was it delayed or withdrawn? Please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:44:25
User closed query 'Per ETRTR: Please confirm rationale for action taken, thanks.' (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:37:39
Query 'Per ETRTR: Please confirm rationale for action taken, thanks.' answered with 'confirm due to patient going to hospital' (Site from CRA).	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 12:59:40
User opened query 'Per ETRTR: Please confirm rationale for action taken, thanks.' (Site from CRA).	(b) (4), (b) (6)	27 Aug 2020 21:21:00
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 12:39:41
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	26 Aug 2020 12:39:09
User entered 'Dose Delayed (DOSE DELAYED)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

None

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:48:43
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'YES' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	30 Sep 2020 19:44:39
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:18:32
User entered '1'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 18:57:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:51

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'PV Query: Per the medical history reported, the subject experienced a drug overdose on 08 AUG 2020, which ended on ?? JUL 2020. Please consider updating the dates or removing from medical history.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 14:38:24
Query 'PV Query: Per the medical history reported, the subject experienced a drug overdose on 08 AUG 2020, which ended on ?? JUL 2020. Please consider updating the dates or removing from medical history.' answered with 'will update ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:16:35
User opened query 'PV Query: Per the medical history reported, the subject experienced a drug overdose on 08 AUG 2020, which ended on ?? JUL 2020. Please consider updating the dates or removing from medical history.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 16:36:26
User closed query 'PV Query: Thank you for providing the discharge summary. The discharge summary lists schizophrenia, PTSD, osteoarthritis and lupus anticoagulant positive as subject's medical histories. Please consider adding them to the Medical History eCRF in EDC.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 15:20:31
User closed query 'PV Query: Thank you for providing the discharge summary. The discharge summary provides fluoxetine, gabapentin, methocarbamol, prazosin and Klonopin (clonazepam) as subject's concomitant medications prior to the event. Please consider adding them to the concomitant medications eCRF in EDC along with all the details such as dates of administration, frequency, route and indications.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 15:20:29
User closed query 'PV Query: Per discharge summary, the subject experienced respiratory failure secondary to Klonopin overdose. Please consider reporting additional SAE Respiratory failure.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 15:20:26

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Per discharge summary, the subject experienced respiratory failure secondary to Klonopin overdose. Please consider reporting additional SAE Respiratory failure.' answered with 'SUB-I IS WAITING FOR PATIENT TO CALL BACK WITH INFORMATION REGARDING THIS SUBJECT' (Site from Safety).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 22:48:04
Query 'PV Query: Thank you for providing the discharge summary. The discharge summary provides fluoxetine, gabapentin, methocarbamol, prazosin and Klonopin (clonazepam) as subject's concomitant medications prior to the event. Please consider adding them to the concomitant medications eCRF in EDC along with all the details such as dates of administration, frequency, route and indications.' answered with 'SUB-I IS WAITING FOR PATIENT TO CALL BACK WITH INFORMATION REGARDING THIS SUBJECT' (Site from Safety).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 22:48:00
Query 'PV Query: Thank you for providing the discharge summary. The discharge summary lists schizophrenia, PTSD, osteoarthritis and lupus anticoagulant positive as subject's medical histories. Please consider adding them to the Medical History eCRF in EDC.' answered with 'SUB-I IS WAITING FOR PATIENT TO CALL BACK WITH INFORMATION REGARDING THIS SUBJECT' (Site from Safety).	Morgan Deal (b) (4) (b) (4)	13 Nov 2020 22:47:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User opened query 'PV Query: Per discharge summary, the subject experienced respiratory failure secondary to Klonopin overdose. Please consider reporting additional SAE Respiratory failure.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:06:07

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Thank you for providing the discharge summary. The discharge summary provides fluoxetine, gabapentin, methocarbamol, prazosin and Klonopin (clonazepam) as subject's concomitant medications prior to the event. Please consider adding them to the concomitant medications eCRF in EDC along with all the details such as dates of administration, frequency, route and indications.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:05:53
User opened query 'PV Query: Thank you for providing the discharge summary. The discharge summary lists schizophrenia, PTSD, osteoarthritis and lupus anticoagulant positive as subject's medical histories. Please consider adding them to the Medical History eCRF in EDC.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 17:05:44
User closed query 'PV Query: The SAE form indicates that atorvastatin was started in 2019 and was stopped on 09 Aug 2020 but the EDC provides the start date as 2020 and is reported as ongoing. Please reconcile and update the EDC if required.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:24:41
User closed query 'PV Query: The SAE form indicates that amlodipine was started in 2019 but the EDC provides the start date as 2020. Please reconcile and update the EDC if required.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:48:50
User closed query 'PV Query: Thank you for providing the discharge summary. The discharge summary provides fluoxetine, gabapentin, methocarbamol, prazosin and Klonopin (clonazepam) as subject's concomitant medications prior to the event. Please consider adding them to the concomitant medications eCRF in EDC along with all the details such as dates of administration, frequency, route and indications.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:48:47
User closed query 'PV Query: Thank you for providing the discharge summary. The discharge summary lists schizophrenia, PTSD, osteoarthritis and lupus anticoagulant positive as subject's medical histories. Please consider adding them to the Medical History eCRF in EDC.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:48:43



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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: Per query response hyperlipidemia started in 2019 but EDC shows that it started in 2020. Please clarify' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:48:39
Query 'PV Query: Thank you for providing the discharge summary. The discharge summary provides fluoxetine, gabapentin, methocarbamol, prazosin and Klonopin (clonazepam) as subject's concomitant medications prior to the event. Please consider adding them to the concomitant medications eCRF in EDC along with all the details such as dates of administration, frequency, route and indications.'	(b) (4), (b) (6)	15 Oct 2020 16:38:46
answered with 'will update' (Site from Safety).		
Query 'PV Query: Thank you for providing the discharge summary. The discharge summary lists schizophrenia, PTSD, osteoarthritis and lupus anticoagulant positive as subject's medical histories. Please consider adding them to the Medical History eCRF in EDC.'	(b) (4), (b) (6)	15 Oct 2020 16:38:36
answered with 'will update' (Site from Safety).		
Query 'PV query: Per query response hyperlipidemia started in 2019 but EDC shows that it started in 2020. Please clarify'	(b) (4), (b) (6)	15 Oct 2020 13:06:57
answered with 'UPDATED' (Site from Safety).		
Query 'PV Query: The SAE form indicates that atorvastatin was started in 2019 and was stopped on 09 Aug 2020 but the EDC provides the start date as 2020 and is reported as ongoing. Please reconcile and update the EDC if required.'	(b) (4), (b) (6)	15 Oct 2020 13:06:14
answered with 'UPDATED' (Site from Safety).		
Query 'PV Query: The SAE form indicates that amlodipine was started in 2019 but the EDC provides the start date as 2020. Please reconcile and update the EDC if required.'	(b) (4), (b) (6)	15 Oct 2020 13:06:07
answered with 'UPDATED' (Site from Safety).		
User opened query 'PV Query: The SAE form indicates that amlodipine was started in 2019 but the EDC provides the start date as 2020. Please reconcile and update the EDC if required.'	(b) (4), (b) (6)	08 Oct 2020 13:45:46
(Site from Safety).		

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The SAE form indicates that atorvastatin was started in 2019 and was stopped on 09 Aug 2020 but the EDC provides the start date as 2020 and is reported as ongoing. Please reconcile and update the EDC if required.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:45:27
User opened query 'PV Query: Thank you for providing the discharge summary. The discharge summary provides fluoxetine, gabapentin, methocarbamol, prazosin and Klonopin (clonazepam) as subject's concomitant medications prior to the event. Please consider adding them to the concomitant medications eCRF in EDC along with all the details such as dates of administration, frequency, route and indications.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:45:09
User opened query 'PV Query: Thank you for providing the discharge summary. The discharge summary lists schizophrenia, PTSD, osteoarthritis and lupus anticoagulant positive as subject's medical histories. Please consider adding them to the Medical History eCRF in EDC.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:44:51
User opened query 'PV query: Per query response hyperlipidemia started in 2019 but EDC shows that it started in 2020. Please clarify' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:43:48
User closed query 'PV Query: Please clarify if the subject had both rhabdomyolysis and respiratory failure secondary to benzodiazepine overdose, and if yes, please add the second event as it required hospitalization.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 14:09:15
User closed query 'PV query: Please confirm if overdose of benzodiazepines was an SAE or AE. If so, please enter into EDC.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 14:09:13
User closed query 'PV query: Please confirm whether medical history of hyperlipidemia started in 2020 or 2019. Please update MH eCRF if applicable. ' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 14:09:07
User closed query 'PV Query: Please provide the subject's creatine kinase level and creatinine? Did the subject have any kidney injury?' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 14:09:01
User closed query 'PV Query: Does the subject have a history of myalgia?' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 14:08:51

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EAB) (1725)

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV query: Was the subject taking statins (other than atorvastatin) or any lipid medications? If so, please provide the names and dosing.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 14:08:49
Query 'PV Query: Please clarify if the subject had both rhabdomyolysis and respiratory failure secondary to benzodiazepine overdose, and if yes, please add the second event as it required hospitalization.' answered with 'NO' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	30 Sep 2020 19:45:52
Query 'PV query: Please confirm if overdose of benzodiazepines was an SAE or AE. If so, please enter into EDC.' answered with 'YES' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	30 Sep 2020 19:45:42
Query 'PV query: Please confirm whether medical history of hyperlipidemia started in 2020 or 2019. Please update MH eCRF if applicable. ' answered with '2019' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	30 Sep 2020 19:45:27
Query 'PV Query: Please provide the subject's creatine kinase level and creatinine? Did the subject have any kidney injury?' answered with 'NO' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	30 Sep 2020 19:45:19
Query 'PV Query: Does the subject have a history of myalgia?' answered with 'NO' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	30 Sep 2020 19:45:16
Query 'PV query: Was the subject taking statins (other than atorvastatin) or any lipid medications? If so, please provide the names and dosing.' answered with 'ATORVASTATIN 10MG' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	30 Sep 2020 19:45:12
Query 'Per ETRTR: 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.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:37:46
Query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 17:37:44

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify if the subject had both rhabdomyolysis and respiratory failure secondary to benzodiazepine overdose, and if yes, please add the second event as it required hospitalization.' (Site from Safety).	(b) (4), (b) (6)	30 Aug 2020 19:00:45
User opened query 'PV query: Please confirm if overdose of benzodiazepines was an SAE or AE. If so, please enter into EDC.' (Site from Safety).	(b) (4), (b) (6)	30 Aug 2020 19:00:39
User opened query 'PV query: Please confirm whether medical history of hyperlipidemia started in 2020 or 2019. Please update MH eCRF if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Aug 2020 19:00:25
User opened query 'PV Query: Please provide the subject's creatine kinase level and creatinine? Did the subject have any kidney injury?' (Site from Safety).	(b) (4), (b) (6)	30 Aug 2020 18:59:07
User opened query 'PV Query: Does the subject have a history of myalgia?' (Site from Safety).	(b) (4), (b) (6)	30 Aug 2020 18:58:53
User opened query 'PV query: Was the subject taking statins (other than atorvastatin) or any lipid medications? If so, please provide the names and dosing.' (Site from Safety).	(b) (4), (b) (6)	30 Aug 2020 18:58:39
User opened query 'Per ETRTR: 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 CRA).	(b) (4), (b) (6)	27 Aug 2020 20:59:40
User opened query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from CRA).	(b) (4), (b) (6)	27 Aug 2020 20:59:03
User entered 'Medical records obtained from the hospital. Patient was admitted for overdose of Benzodiazepines causing respiratory failure.' reason for change: Data Entry Error	Shanice Bennett (b) (4)	26 Aug 2020 12:44:53
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Aug 2020 18:57:53

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Aug 2020 18:57:53
User entered 'SAE was submitted on 25Aug200.' reason for change: Data Entry Error	Shanice Bennett (b) (4)	25 Aug 2020 18:57:53
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	25 Aug 2020 18:57:11
	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11
	(b) (4)	

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:49:51**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 18:57:11

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Folder: Adverse Events

Form: Adverse Events (1)

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Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 18:57:11

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**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:49:51**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	25 Aug 2020 18:58:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:49:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 17:05:43
User entered 'USA-US051-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	12 Nov 2020 17:05:28

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Pulmonary failure - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 19:16:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. DataPoint Verified.	Coder Import (b) (4)	12 Nov 2020 19:16:34
	(b) (4), (b) (6)	12 Nov 2020 14:33:42
Data point term sent to Coder	System	11 Nov 2020 16:46:30
User entered 'LUNG FAILURE'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:46:29

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:49:51**

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:46:29

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US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '19 Aug 2020'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:46:29

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:49:51**

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:46:29

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US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:46:29



US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '19 Aug 2020'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:46:29



US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:49:55
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:14:02
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:14:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:49:58
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:14:02
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:14:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per CDM, re-query: Response noted. Please update the action taken for investigational product for log lines 2 and 3 as there is only 1 record required for IP Withdrawn.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 04:40:02
Query 'Per CDM, re-query: Response noted. Please update the action taken for investigational product for log lines 2 and 3 as there is only 1 record required for IP Withdrawn.' answered with 'will update' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 20:16:47
User opened query 'Per CDM, re-query: Response noted. Please update the action taken for investigational product for log lines 2 and 3 as there is only 1 record required for IP Withdrawn.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:29:52
User closed query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:29:52
Query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' answered with 'the main reason was the overdose of medication ' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 20:33:07
User opened query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 22:36:43
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:51:24
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:19:06
User entered '0' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:51:30
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:19:06
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:19:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:46:29



US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:51:33
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:14:02
User entered 'klonapin overdose' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:14:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Nov 2020 16:46:55
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Nov 2020 16:46:55
User entered 'SAE UPDATED' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:46:55
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Nov 2020 16:46:29
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:46:29

US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 16:46:29

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US3022031

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:49:51

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 16:46:29

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**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:49:51**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 16:46:29

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US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:51:38
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 17:06:03
User entered 'USA-US051-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	12 Nov 2020 17:06:00

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4)	12 Nov 2020 14:33:42
	(b) (4), (b) (6)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 17:04:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 17:04:33
	(b) (4)	
Data point term sent to Coder	System	11 Nov 2020 16:48:40
User entered 'PNEUMONIA'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:48:06



US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:48:06

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:51**

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:48:06

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US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '19 Aug 2020'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:48:06

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:51**

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:48:06

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US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '19 Aug 2020'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:48:06



US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:52:03
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:15:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:15:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:52:05
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:15:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:15:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:52:12
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:19:47
User entered '0' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:19:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 16:48:06



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:52:14
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:19:47
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:19:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:52:18
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:15:37
User entered 'SAE Due to Klonapin overdose' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:15:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'SAE ENTERED'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 16:48:06

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US3022031

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:51

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 16:48:06

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**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:49:51**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 16:48:06

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:49:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:22
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Please add klonopin and fluoxetine per ConMed log.' (Site from CRA).	(b) (4)	16 Nov 2020 02:19:01
Query 'Please add klonopin and fluoxetine per ConMed log.' answered with 'added ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 22:28:30
User opened query 'Please add klonopin and fluoxetine per ConMed log.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 14:49:51
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:35:18
User entered 'Yes (Y)'	Stella Yoon (b) (4)	28 Jul 2020 00:13:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Jul 2020 00:15:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Jul 2020 00:15:01
Data point term sent to Coder	System	28 Jul 2020 00:13:50
User entered 'atorvastatin'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:53
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:54
User entered 'hyperlipidemia'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:25:32
User entered '40' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:25:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:40:56
User entered '10'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:58
User entered 'mg (mg)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:41:02
User entered empty.	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:41:10
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:41:03
User entered 'once daily (QD)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:28



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:41:08
User entered empty.	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:14
User entered 'Oral (ORAL)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:16
User entered empty.	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:42:33
User entered 'UN UNK 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 13:05:10
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERLIPIDEMIA (2020). Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:26:04
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERLIPIDEMIA (2020). Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4)	22 Sep 2020 19:08:41
User entered 'UN UNK 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	22 Sep 2020 19:08:32
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERLIPIDEMIA (2020). Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 15:36:49
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 12:42:42
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Stella Yoon (b) (4)	28 Jul 2020 00:14:16
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	28 Jul 2020 00:13:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:36
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4)	16 Nov 2020 02:17:32
User closed query 'Please confirm. Per source end date 09Aug2020.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:17:29
Query 'Please confirm. Per source end date 09Aug2020.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 19:29:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 19:29:05
User opened query 'Please confirm. Per source end date 09Aug2020.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 14:35:58
User entered 'Yes (Y)'	Stella Yoon (b) (4)	28 Jul 2020 00:13:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:17:30
User entered '09 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 19:29:05
User entered empty.	Stella Yoon (b) (4)	28 Jul 2020 00:13:28



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:40
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User entered '1'	System	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User entered '1'	System	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:48:52
User entered '804 (804)'	System	28 Jul 2020 00:13:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:37
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.	Coder Import (b) (4) (b) (4)	28 Jul 2020 16:18:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jul 2020 16:18:13
Data point term sent to Coder	System	28 Jul 2020 00:14:51
User entered 'amlodipine'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:51

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:39
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:51

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:41
User entered 'hypertension'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:51

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Un-verified.	(b) (4)	
	Shanice Bennett (b) (4)	16 Nov 2020 18:25:18
	(b) (4)	
User entered '5' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:25:18
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:43:43
User entered '10'	Stella Yoon (b) (4)	28 Jul 2020 00:13:51
	(b) (4)	



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:45
User entered 'mg (mg)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:51

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:46
User entered empty.	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:51

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:48
User entered 'once daily (QD)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:51

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:01
User entered empty.	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:51

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:02
User entered 'Oral (ORAL)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:51

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:04
User entered empty.	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:51

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:13
User entered 'UN UNK 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 13:05:21
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION (2020). Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:26:16
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION (2020). Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'UPDATED' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	22 Sep 2020 19:09:16
User entered 'UN UNK 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	22 Sep 2020 19:09:04
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition of HYPERTENSION (2020). Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 15:37:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 12:42:47
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:14:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	28 Jul 2020 00:13:51
User entered 'un UNK 2019'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:51

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:15
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:51



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:17
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:51

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:19
User entered empty.	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:51

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:21
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:13:51

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	28 Jul 2020 00:13:51

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**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:49:51**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	28 Jul 2020 00:13:51

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Jul 2020 00:13:51

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:22:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:22:07
Data point term sent to Coder	System	05 Aug 2020 20:42:49
User entered 'OXYCODONE ACETAMINOPHEN'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:36
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:37
User entered 'BACK PAIN'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:39
User entered '10/325'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:41
User entered 'mg (mg)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:46
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:47
User entered 'as needed (PRN)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:49
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:51
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:53
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:55
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 08:48:30
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'CORRECT' (Site from System).	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 20:42:09
User entered 'UN UNK 2016'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:45:01
User entered '0'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:45:04
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:45:06
User entered empty.	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:45:08
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	05 Aug 2020 20:42:09

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:49:51**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:42:09

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:42:09

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:42:09

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 20:13:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 20:13:06
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:29
User closed query 'Please confirm. This is not on the ConMed log.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 15:47:27
Data point term sent to Coder Coding entries removed.	System	16 Nov 2020 18:25:56
	Shanice Bennett (b) (4)	16 Nov 2020 18:25:00
User entered 'Aopiprazole' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:25:00
Query 'Please confirm. This is not on the ConMed log.' answered with 'this is on con med log page 2' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 22:27:15
User opened query 'Please confirm. This is not on the ConMed log.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 14:38:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Oct 2020 04:19:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Oct 2020 04:19:42
Data point term sent to Coder	System	30 Sep 2020 19:02:41
User entered 'Aripiprazole'	Stella Yoon (b) (4)	30 Sep 2020 19:02:22

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:32
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:02:22

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per DM CLR: Con Med AOPIPRAZOLE was added/changed on 17 AUG 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)	04 Jan 2021 07:47:37
Query 'Per DM CLR: Con Med AOPIPRAZOLE was added/changed on 17 AUG 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 'This was a past mh that was discovered when SAE occurred' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 21:24:42
User opened query 'Per DM CLR: Con Med AOPIPRAZOLE was added/changed on 17 AUG 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)	09 Dec 2020 02:40:35
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:35
User entered 'Schizoaffective disorder'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:02:22

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication, and it appear to exceed the maximum recommended daily dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 01:43:38
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication, and it appear to exceed the maximum recommended daily dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'this is correct ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 16:27:41
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication, and it appear to exceed the maximum recommended daily dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 06:00:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:47:37
User entered '40' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:25:00
User entered '10'	(b) (4) Stella Yoon (b) (4)	30 Sep 2020 19:02:22

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:40
User entered 'mg (mg)'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:02:22

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:44
User entered empty.	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:02:22

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:48
User entered 'once daily (QD)'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:02:22

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:51
User entered empty.	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:02:22



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:54
User entered 'Oral (ORAL)'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:02:22

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:47:58
User entered empty.	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:02:22

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query ' Per CDM CLR(Requery) : Please note the AE (SCHIZOAFFECTIVE DISORDER) has a start date UNJUN2007 which does not match with the start date of this medication (9sep2020), kindly clarify if the dates are correct, if not correct if yes kindly clarify if there was a WORSENING/EXACERBATION of the medical history. Thanks ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 05:24:06
	(b) (4), (b) (6)	19 Nov 2020 15:48:01
User entered '17 Aug 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:25:00
Query ' Per CDM CLR(Requery) : Please note the AE (SCHIZOAFFECTIVE DISORDER) has a start date UNJUN2007 which does not match with the start date of this medication (9sep2020), kindly clarify if the dates are correct, if not correct if yes kindly clarify if there was a WORSENING/EXACERBATION of the medical history. Thanks ' answered with 'updated' (Site from DM).	(b) (4) Shanice Bennett (b) (4)	13 Nov 2020 22:55:51
User entered 'un UNK 2007' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 22:55:45
User opened query ' Per CDM CLR(Requery) : Please note the AE (SCHIZOAFFECTIVE DISORDER) has a start date UNJUN2007 which does not match with the start date of this medication (9sep2020), kindly clarify if the dates are correct, if not correct if yes kindly clarify if there was a WORSENING/EXACERBATION of the medical history. Thanks ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:09:38

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med ARIPIPRAZOLE was added on 9 SEP 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)	13 Nov 2020 05:09:38
Query 'Per DM CLR: Con Med ARIPIPRAZOLE was added on 9 SEP 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.	(b) (4), (b) (6)	11 Nov 2020 16:41:30
' answered with 'ADDED AE' (Site from DM). User opened query 'Per DM CLR: Con Med ARIPIPRAZOLE was added on 9 SEP 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.	(b) (4), (b) (6)	03 Nov 2020 20:41:30
' (Site from DM). User entered '9 Sep 2020'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:02:22

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:03
User entered '0'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:02:22

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:08
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:02:22

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:13
User entered empty.	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:02:22

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:16
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:02:22



**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:49:51**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 19:02:22

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**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:49:51**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 19:02:22

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 19:02:22

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User closed query 'Per DM CLR: Con Med FLUOXETINE was added/changed on 17 AUG 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)	02 Mar 2021 13:41:37
Query 'Per DM CLR: Con Med FLUOXETINE was added/changed on 17 AUG 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 THESE JUST WERE NOT RECORDED IN SCREENING' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 19:44:18
User opened query 'Per DM CLR: Con Med FLUOXETINE was added/changed on 17 AUG 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)	26 Feb 2021 01:56:59
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Nov 2020 06:38:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Nov 2020 06:38:55
Data point term sent to Coder	System	12 Nov 2020 22:26:35
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 22:26:27

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

Name of Medication

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	12 Nov 2020 22:26:27
User entered 'fluoxetine' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 22:26:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 21:53:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 21:53:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:39:33
Data point term sent to Coder	System	11 Nov 2020 16:43:28
Coding entries removed.	(b) (4), (b) (6)	11 Nov 2020 16:43:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:32:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:32:06
Data point term sent to Coder	System	30 Sep 2020 19:04:49
User entered 'duloxetine'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:39:35
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per DM CLR-REQUERY: Response noted, however, please note that Con Med FLUOXETINE was added/changed on 17 AUG 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)	04 Jan 2021 07:48:48
Query 'Per DM CLR-REQUERY: Response noted, however, please note that Con Med FLUOXETINE was added/changed on 17 AUG 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 'This was a past mh that was found after SAE' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 21:25:32
User opened query 'Per DM CLR-REQUERY: Response noted, however, please note that Con Med FLUOXETINE was added/changed on 17 AUG 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)	09 Dec 2020 02:46:44
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:39:37
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)	12 Nov 2020 04:30:08

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
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 'UPDATED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:43:08
User entered 'SCHIZOPHERNIA/ PTSD' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 16:43:03
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)	03 Nov 2020 20:42:12
User entered 'mood stabilizer'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:18



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:39:39
User entered '40'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:39:42
User entered 'mg (mg)'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:39:43
User entered empty.	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:39:45
User entered 'once daily (QD)'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:39:47
User entered empty.	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:39:48
User entered 'Oral (ORAL)'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:39:50
User entered empty.	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:18:31
User closed query 'Please confirm. Per source start date is 17Aug2020.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:18:29
Query 'Please confirm. Per source start date is 17Aug2020.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 22:26:44
User entered '17 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 22:26:40
User opened query 'Please confirm. Per source start date is 17Aug2020.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 14:38:48
User entered '9 Sep 2020'	Stella Yoon (b) (4)	30 Sep 2020 19:04:18



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:39:54
User entered '0'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 18:37:59
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:39:56
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:59
User entered '15 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 18:37:59
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:39:58
User entered empty.	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:39:59
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User entered '1'	System	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User entered '1'	System	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:00
User entered '804 (804)'	System	30 Sep 2020 19:04:18

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 07:21:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Nov 2020 07:21:22
Data point term sent to Coder	System	16 Nov 2020 18:28:03
Coding entries removed.	Shanice Bennett (b) (4)	16 Nov 2020 18:27:53
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:27:53
Coding entries removed.	Shanice Bennett (b) (4)	16 Nov 2020 18:27:53
User entered 'Rivaroxaban' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:40:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 23:17:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 23:17:37
Data point term sent to Coder	System	11 Nov 2020 16:44:29
User entered 'ARIPRAZOLE'	(b) (4), (b) (6)	11 Nov 2020 16:44:09



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:09
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:44:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:27:53
User entered 'Hypercoagulable stables' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:27:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:40:11
User entered 'SCHIZOPHERNIA/PTSD'	(b) (4), (b) (6)	11 Nov 2020 16:44:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Un-verified.	(b) (4)	
	Shanice Bennett (b) (4)	16 Nov 2020 18:27:53
	(b) (4)	
User entered '20' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:27:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:40:13
	(b) (4), (b) (6)	
User entered '40'	(b) (4), (b) (6)	11 Nov 2020 16:44:09
	(b) (4), (b) (6)	

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:15
User entered 'mg (mg)'	(b) (4), (b) (6)	11 Nov 2020 16:44:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:17
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:44:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:19
User entered 'once daily (QD)'	(b) (4), (b) (6)	11 Nov 2020 16:44:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:20
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:44:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	11 Nov 2020 16:44:09



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:26
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:44:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Un-verified.	(b) (4)	
	Shanice Bennett (b) (4)	16 Nov 2020 18:27:53
	(b) (4)	
User entered 'UN UNK 1991' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:27:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:40:31
	(b) (4)	
User entered '17 Aug 2020'	(b) (4), (b) (6)	11 Nov 2020 16:44:09
	(b) (4)	

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:33
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 16:44:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:44:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:38
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:44:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:40:40
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:44:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 16:44:09

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 16:44:09

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 16:44:09

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	13 Nov 2020 00:22:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:22:36
Data point term sent to Coder	System	12 Nov 2020 22:28:36
User entered 'duloxetine'	(b) (4), (b) (6)	12 Nov 2020 22:28:16

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:28:16

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per DM CLR: Con Med DULOXETINE was added/changed on 17 AUG 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)	04 Jan 2021 07:49:06
Query 'Per DM CLR: Con Med DULOXETINE was added/changed on 17 AUG 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 'THIS was a past mh that was found after SAE' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 21:25:48
User opened query 'Per DM CLR: Con Med DULOXETINE was added/changed on 17 AUG 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)	09 Dec 2020 02:47:38
User entered 'schizophrenia/ptsd'	(b) (4), (b) (6)	12 Nov 2020 22:28:16

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '40'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:28:16

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:28:16

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:28:16

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:28:16



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:28:16

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:28:16

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:28:16

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:28:16

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:28:16

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:28:16

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:28:16

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:28:16



**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:49:51**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 22:28:16

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**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:49:51**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 22:28:16

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 22:28:16

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM, PRODUCTSYNONYM: KLONOPIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 22:30:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 22:30:35
Data point term sent to Coder	System	12 Nov 2020 22:29:37
User entered 'klonopin'	(b) (4), (b) (6)	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Per CDM, DM CLR re-query: Response noted; however ANXIETY is not recorded on the MH/AE page. Please keep this query open until an update is made, else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 16:41:25
Query 'Per CDM, DM CLR re-query: Response noted; however ANXIETY is not recorded on the MH/AE page. Please keep this query open until an update is made, else clarify.' answered with 'added' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 17:42:32
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 14:29:02
User opened query 'Per CDM, DM CLR re-query: Response noted; however ANXIETY is not recorded on the MH/AE page. Please keep this query open until an update is made, else clarify.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 14:29:00
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' answered with 'Will update' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 21:26:00
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 02:49:15
User entered 'anxiety'	(b) (4), (b) (6)	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '1'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:29:23



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '10 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:29:23



**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:49:51**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User entered empty.	System	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User entered empty.	System	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:04
User entered empty.	System	12 Nov 2020 22:29:23

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: PRAZOSIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Nov 2020 18:29:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 18:29:45
Data point term sent to Coder	System	16 Nov 2020 18:29:05
User entered 'prazosin'	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:28:50

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	Shanice Bennett (b) (4)	16 Nov 2020 18:28:50

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'nightmares'	(b) (4) Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:28:50



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '1'	Shanice Bennett (b) (4)	16 Nov 2020 18:28:50

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'mg (mg)'	Shanice Bennett (b) (4)	16 Nov 2020 18:28:50

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) Shanice Bennett (b) (4)	16 Nov 2020 18:28:50
	(b) (4)	

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'once daily (QD)'	Shanice Bennett (b) (4)	16 Nov 2020 18:28:50

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) Shanice Bennett (b) (4)	16 Nov 2020 18:28:50
	(b) (4)	

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	16 Nov 2020 18:28:50

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) Shanice Bennett (b) (4)	16 Nov 2020 18:28:50
	(b) (4)	

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'un Jun 2020'	(b) (4) Shanice Bennett (b) (4)	16 Nov 2020 18:28:50
	(b) (4)	



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:28:50

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	16 Nov 2020 18:28:50

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) Shanice Bennett (b) (4)	16 Nov 2020 18:28:50
	(b) (4)	

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	Shanice Bennett (b) (4)	16 Nov 2020 18:28:50

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:49:51

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 18:28:50

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**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:49:51**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 18:28:50

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US3022031

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:49:51**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 18:28:50

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Jan 2021 18:39:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Jan 2021 18:39:00
Data point term sent to Coder	System	26 Jan 2021 18:37:50
User entered 'INFLUENZA VACCINE'	(b) (4), (b) (6)	26 Jan 2021 18:36:53



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'INFLUENZA PREVENTION'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0.5'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:53



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'UN Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'UN Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User entered empty.	System	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User entered empty.	System	26 Jan 2021 18:36:53



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:34:09
User entered empty.	System	26 Jan 2021 18:36:53

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med DULOXETINE was added/changed on 16 JAN 2021. 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)	02 Mar 2021 12:58:23
Query 'Per DM CLR: Con Med DULOXETINE was added/changed on 16 JAN 2021. 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 'THIS IS NOT WORSEING ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 19:44:49
User opened query 'Per DM CLR: Con Med DULOXETINE was added/changed on 16 JAN 2021. 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)	26 Feb 2021 01:57:40
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Jan 2021 18:39:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Jan 2021 18:39:01
Data point term sent to Coder	System	26 Jan 2021 18:37:52
User entered 'DULOXETINE'	(b) (4), (b) (6)	26 Jan 2021 18:37:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'DEPRESSION'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '30'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:28



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:28

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:37:28



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 18:37:28

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 18:37:28

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:49:51

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Jan 2021 18:37:28

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US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:49:51

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:22
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:27
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:18:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	16 Nov 2020 18:18:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:50:12
User entered 'No (N)'	Shanice Bennett (b) (4)	12 Oct 2020 18:08:36
	(b) (4)	

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:49:51

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered '10 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:22:46

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:49:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:54:26
User closed query 'Per DM CLR: Please specify the location of CT SCAN (e.g. CT SCAN ON ABDOMEN, CT SCAN ON CHEST, etc.). Update Concomitant Procedure eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 13:15:53
Query 'Per DM CLR: Please specify the location of CT SCAN (e.g. CT SCAN ON ABDOMEN, CT SCAN ON CHEST, etc.). Update Concomitant Procedure eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 19:43:23
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 19:43:01
Signature has been broken.	(b) (4), (b) (6)	01 Mar 2021 19:43:01
User entered 'CT SCAN OF CHEST' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 19:43:01
User opened query 'Per DM CLR: Please specify the location of CT SCAN (e.g. CT SCAN ON ABDOMEN, CT SCAN ON CHEST, etc.). Update Concomitant Procedure eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 13:50:23
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered 'CT Scan'	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:22:46

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:22:46

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:49:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:22:46



US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:49:51

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered '10 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:23:17

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:49:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered 'Chest Xray'	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:23:17

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:23:17

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:49:51

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:23:17

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:49:51

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered '10 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:23:44

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:49:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered 'Mechanical Ventilator'	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:23:44

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:49:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:23:44

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:49:51

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:26:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:23:44



US3022031

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:49:51

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:55:06
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered '29 Sep 2020'	Shanice Bennett (b) (4) (b) (4)	12 Oct 2020 18:08:14

US3022031

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:49:51

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:55:06
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:41:17
User entered 'SAE (specify) (SAE)'	Shanice Bennett (b) (4) (b) (4)	12 Oct 2020 18:08:14

US3022031

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:49:51

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:55:06
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:54:26
User closed query 'Per CDM: Per sponsor review, please update specify field to include both AE and number. (i.e. AE#1).' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:00:58
Query 'Per CDM: Per sponsor review, please update specify field to include both AE and number. (i.e. AE#1).' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 18:31:08
Signature has been broken.	(b) (4), (b) (6)	04 Mar 2021 18:30:56
User entered 'AE#1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 18:30:56
User opened query 'Per CDM: Per sponsor review, please update specify field to include both AE and number. (i.e. AE#1).' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:09:50
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	(b) (4) System	12 Oct 2020 18:08:27
User entered '#1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	12 Oct 2020 18:08:27
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	(b) (4) System	12 Oct 2020 18:08:14
User entered empty.	Shanice Bennett (b) (4)	12 Oct 2020 18:08:14

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'USA-US051-2020-MRNA-1273-P301000001'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.		16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:45
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 13:52:59
User entered 'US' (non-conformant).	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '7'	(b) (4)	30 Nov 2020 14:38:57
User entered '6'	System	17 Nov 2020 13:17:18
User entered '5'	System	12 Nov 2020 17:06:23
User entered '4'	System	19 Oct 2020 15:26:49
User entered '3'	System	16 Oct 2020 12:49:09
User entered '2'	System	26 Aug 2020 13:53:14
User entered '1'	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'USA-US051-2020-MRNA-1273-P301000001'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:45
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 13:52:59
User entered 'US' (non-conformant).	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '7'	(b) (4)	30 Nov 2020 14:38:57
User entered '6'	System	17 Nov 2020 13:17:18
User entered '5'	System	12 Nov 2020 17:06:23
User entered '4'	System	19 Oct 2020 15:26:49
User entered '3'	System	16 Oct 2020 12:49:09
User entered '2'	System	26 Aug 2020 13:53:14
User entered '1'	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:49:51

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
User entered '26/Aug/2020 07:53'	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:49:51

**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.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 13:52:59
User entered '1'	(b) (4), (b) (6)	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'USA-US051-2020-MRNA-1273-P301000001'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6) '	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:45
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 13:52:59
User entered 'US' (non-conformant).	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '7'	(b) (4)	30 Nov 2020 14:38:57
User entered '6'	System	17 Nov 2020 13:17:18
User entered '5'	System	12 Nov 2020 17:06:23
User entered '4'	System	19 Oct 2020 15:26:49
User entered '3'	System	16 Oct 2020 12:49:09
User entered '2'	System	26 Aug 2020 13:53:14
User entered '1'	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:49:51

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
User entered '26/Aug/2020 09:53'	System	26 Aug 2020 13:53:14

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:49:51

**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.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
User entered '1'	(b) (4), (b) (6)	26 Aug 2020 13:53:14

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'USA-US051-2020-MRNA-1273-P301000001'	System	26 Aug 2020 11:50:48



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6) '	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:45
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 13:52:59
User entered 'US' (non-conformant).	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '7'	(b) (4)	30 Nov 2020 14:38:57
User entered '6'	System	17 Nov 2020 13:17:18
User entered '5'	System	12 Nov 2020 17:06:23
User entered '4'	System	19 Oct 2020 15:26:49
User entered '3'	System	16 Oct 2020 12:49:09
User entered '2'	System	26 Aug 2020 13:53:14
User entered '1'	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:49:51

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
User entered '16/Oct/2020 12:49'	System	16 Oct 2020 12:49:09



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:49:51

**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.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 15:26:39
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 12:49:09

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'USA-US051-2020-MRNA-1273-P301000001'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:45
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 13:52:59
User entered 'US' (non-conformant).	System	26 Aug 2020 11:53:02



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '7'	(b) (4)	30 Nov 2020 14:38:57
User entered '6'	System	17 Nov 2020 13:17:18
User entered '5'	System	12 Nov 2020 17:06:23
User entered '4'	System	19 Oct 2020 15:26:49
User entered '3'	System	16 Oct 2020 12:49:09
User entered '2'	System	26 Aug 2020 13:53:14
User entered '1'	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:49:51

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
User entered '19/Oct/2020 15:26'	System	19 Oct 2020 15:26:49

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:49:51

**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.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 15:26:57
User entered '1'	(b) (4), (b) (6)	19 Oct 2020 15:26:49

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'USA-US051-2020-MRNA-1273-P301000001'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:45
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 13:52:59
User entered 'US' (non-conformant).	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '7'	(b) (4)	30 Nov 2020 14:38:57
User entered '6'	System	17 Nov 2020 13:17:18
User entered '5'	System	12 Nov 2020 17:06:23
User entered '4'	System	19 Oct 2020 15:26:49
User entered '3'	System	16 Oct 2020 12:49:09
User entered '2'	System	26 Aug 2020 13:53:14
User entered '1'	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:49:51

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:15:29
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
	(b) (4)	
User entered '12/Nov/2020 17:06'	System	12 Nov 2020 17:06:23

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:49:51

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:15:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:17:08
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 17:06:23

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'USA-US051-2020-MRNA-1273-P301000001'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:45
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 13:52:59
User entered 'US' (non-conformant).	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '7'	(b) (4)	30 Nov 2020 14:38:57
User entered '6'	System	17 Nov 2020 13:17:18
User entered '5'	System	12 Nov 2020 17:06:23
User entered '4'	System	19 Oct 2020 15:26:49
User entered '3'	System	16 Oct 2020 12:49:09
User entered '2'	System	26 Aug 2020 13:53:14
User entered '1'	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:49:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:15:43
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
	(b) (4)	
User entered '17/Nov/2020 08:17'	System	17 Nov 2020 13:17:18

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:49:51

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:15:37
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:38:44
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 13:17:18

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'USA-US051-2020-MRNA-1273-P301000001'	System	26 Aug 2020 11:50:48



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

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Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

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Form: Safety Report Form

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'Yes (Y)'	System	26 Aug 2020 11:50:48

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Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

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Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

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Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered 'No (N)'	System	26 Aug 2020 11:50:48

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Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Paul'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48



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Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Bradley'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

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Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '340 Eisenhower Dr.'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'Savannah'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered 'GA'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:48:59
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:40:04
Amendment Manager: User entered '31406'	System	14 Sep 2020 21:40:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 11:52:55
User entered (b) (6)	System	26 Aug 2020 11:50:48

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:26:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:07:45
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 13:52:59
User entered 'US' (non-conformant).	System	26 Aug 2020 11:53:02

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Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
User entered '7'	(b) (4)	30 Nov 2020 14:38:57
User entered '6'	System	17 Nov 2020 13:17:18
User entered '5'	System	12 Nov 2020 17:06:23
User entered '4'	System	19 Oct 2020 15:26:49
User entered '3'	System	16 Oct 2020 12:49:09
User entered '2'	System	26 Aug 2020 13:53:14
User entered '1'	System	26 Aug 2020 11:53:02

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:49:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:15:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
	(b) (4)	
User entered '30/Nov/2020 09:38'	System	30 Nov 2020 14:38:57



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Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:49:51

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:15:49
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:41:17
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	30 Nov 2020 14:38:57