

US3022031 (Prod: Meridian Clinical Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 08:40:47

All time stamps listed in this document are displayed in GMT

**US3022031**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 08:40:47**

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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

Generated On: 26 Nov 2020 08:40:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:47

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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:47

Date of Informed Consent ( <i>dd MMM yyyy</i> )	27 JUL 2020
Month and Year of Informed Consent (derived)	JUL 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 08:40:47**

[Did the participant meet all eligibility criteria?](#)

Yes ☒

No ☐

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**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 26 Nov 2020 08:40:47**

[Were any significant conditions reported?](#)

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:47

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)

Generated On: 26 Nov 2020 08:40:47

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)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:40:47

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)

Generated On: 26 Nov 2020 08:40:47

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)

Generated On: 26 Nov 2020 08:40:47

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:40:47

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)

Generated On: 26 Nov 2020 08:40:47

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)

Generated On: 26 Nov 2020 08:40:47

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)

Generated On: 26 Nov 2020 08:40:47

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 (10)

Generated On: 26 Nov 2020 08:40:47

Condition	MUSCLE SPASMS
Start date (dd MMM yyyy)	30 SEP 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 08:40:47

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)

Generated On: 26 Nov 2020 08:40:47

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)

Generated On: 26 Nov 2020 08:40:47

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)

Generated On: 26 Nov 2020 08:40:47

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)

Generated On: 26 Nov 2020 08:40:47

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 (16)

Generated On: 26 Nov 2020 08:40:47

Condition	DRUG OVERDOSE
Start date (dd MMM yyyy)	08 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	19 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 08:40:47

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)

Generated On: 26 Nov 2020 08:40:47

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: Vital Signs

Generated On: 26 Nov 2020 08:40:47

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)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:47

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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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

**Specify**

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

<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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:40:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:47

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 ☒

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 26 Nov 2020 08:40:47**

Height	ND - Not Done
Weight	ND - Not Done



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:47

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 JUL 2020
Time of assessment (00:00-23:59)	17:25 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 17:25
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:47

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 JUL 2020
Time of assessment (00:00-23:59)	19:58 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 19:58
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:47

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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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:47

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

Generated On: 26 Nov 2020 08:40:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	27 JUL 2020
Collection time ( <i>00:00-23:59</i> )	18:05 (24 HR)
Collection date and time (derived)	27 JUL 2020 18:05

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:40:47

Collection date (dd MMM yyyy)			27 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	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

Generated On: 26 Nov 2020 08:40:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 26 Nov 2020 08:40:47

**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



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 26 Nov 2020 08:40:47

**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

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

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: 26 Nov 2020 08:40:47

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

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: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.6 °F
Was any <b>MEDICATION TAKEN today for pain or fever</b> ?	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	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: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.7 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

02 AUG 2020 17:38

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PC Open Date & Time

02 AUG 2020 12:00

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PC Close Date & Time

03 AUG 2020 11:59

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US3022031

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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.**

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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.**

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47

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

No ☒

Yes ☐

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

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47

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: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47

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: 26 Nov 2020 08:40:47

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: 26 Nov 2020 08:40:47

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: 26 Nov 2020 08:40:47

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: 26 Nov 2020 08:40:47

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		30 JUL 2020 12:00
<hr/>		
PC Close Date & Time		31 JUL 2020 11:59
<hr/>		

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47

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: 26 Nov 2020 08:40:47

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: 26 Nov 2020 08:40:47

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		01 AUG 2020 12:00
<hr/>		
PC Close Date & Time		02 AUG 2020 11:59
<hr/>		

US3022031

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		02 AUG 2020 12:00
PC Close Date & Time		03 AUG 2020 11:59
<hr/>		

US3022031

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:47

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

Generated On: 26 Nov 2020 08:40:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:47

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

Generated On: 26 Nov 2020 08:40:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:47

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

Generated On: 26 Nov 2020 08:40:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:47

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)	29 SEP 2020
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 13:36
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)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:47

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Generated On: 26 Nov 2020 08:40:47

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

Generated On: 26 Nov 2020 08:40:47

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

Generated On: 26 Nov 2020 08:40:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	29 SEP 2020
Collection time ( <i>00:00-23:59</i> )	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

Generated On: 26 Nov 2020 08:40:47

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	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

Generated On: 26 Nov 2020 08:40:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:47

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

Generated On: 26 Nov 2020 08:40:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:47

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

Generated On: 26 Nov 2020 08:40:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:47

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

Generated On: 26 Nov 2020 08:40:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022031

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:47

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

Generated On: 26 Nov 2020 08:40:47

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

Generated On: 26 Nov 2020 08:40:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	28 OCT 2020
Collection time ( <i>00:00-23:59</i> )	14:24 (24 HR)
Collection date and time (derived)	28 OCT 2020 14:24

US3022031

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:47

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: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

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: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47

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: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47

**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: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 SEP 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2020 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

30 SEP 2020 00:01

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[Patient Cloud Close Date & Time](#)

04 OCT 2020 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2020 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2020 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2020 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2020 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2020 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 103

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 NOV 2020 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

11 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2020 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 NOV 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2020 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2020 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 138

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2020 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 DEC 2020 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 152

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

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

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

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

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

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

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

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2020 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JAN 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JAN 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

20 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JAN 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 194

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

No ☐

Yes ☐

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

No ☐

Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 FEB 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 FEB 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 FEB 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 FEB 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 208

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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03 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 MAR 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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24 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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31 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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07 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 APR 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 APR 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 APR 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[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: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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02 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUN 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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14 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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11 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 AUG 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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25 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 SEP 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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01 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 DEC 2021 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[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: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JAN 2022 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 JAN 2022 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JAN 2022 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 FEB 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 565

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 FEB 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 FEB 2022 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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23 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 FEB 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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09 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 MAR 2022 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 MAR 2022 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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30 MAR 2022 00:01

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03 APR 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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20 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 APR 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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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

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUN 2022 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

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: 26 Nov 2020 08:40:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JUL 2022 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUL 2022 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[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: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
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<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: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 SEP 2022 23:59

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US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

**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: 26 Nov 2020 08:40:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 SEP 2022 23:59

US3022031

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:40:47

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

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

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[Patient Cloud Open Date & Time](#)

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28 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 OCT 2022 23:59

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**US3022031**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:40:47**

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 85 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:40:47**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022031

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 08:40:47

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: 26 Nov 2020 08:40:47**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3022031

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:40:47

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:47

AEID	USA-US051-2020-MRNA-1273-P30 1000001
Adverse event	OVERDOSE OF KLONOPIN
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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:47

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
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)

Generated On: 26 Nov 2020 08:40:47

AEID	USA-US051-2020-MRNA-1273-P30 1000001
Adverse event	LUNG FAILURE
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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:40:47

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:40:47

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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:40:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:40:47

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

Yes ☒

No ☐

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

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US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:47

Name of Medication	ATORVASTATIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERLIPIDEMIA
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:47

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	09 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:47

Name of Medication	AMLODIPINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HYPERTENSION
Dose per administration	5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:40:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:47

Name of Medication	OXYCODONE ACETAMINOPHEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	BACK PAIN
Dose per administration	10/325
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:47

	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="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:47

Name of Medication	AOIPRAZOLE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SCHIZOAFFECTIVE DISORDER
Dose per administration	40
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:40:47

Name of Medication	FLUOXETINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SCHIZOPHERNIA/ PTSD
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:40:47

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		17 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:40:47

Name of Medication	RIVAROXABAN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERCOAGULABLE STABLES
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 08:40:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:40:47

Name of Medication	DULOXETINE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	SCHIZOPHRENIA/PTSD
Dose per administration	40
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:40:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:40:47

Name of Medication	KLONOPIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANXIETY
Dose per administration	1
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:40:47

	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"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)		10 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		19 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<hr/>
Interval Dosage Unit Number (derived)		<hr/>
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:40:47

Name of Medication	PRAZOSIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	NIGHTMARES
Dose per administration	1
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 08:40:47

	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"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
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 Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:40:47

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.



US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 08:40:47

Procedure/Surgery date ( <i>dd MMM yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
10 AUG 2020	CT SCAN	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

Generated On: 26 Nov 2020 08:40:47

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

#1

US3022031

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:40:47

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

Generated On: 26 Nov 2020 08:40:47

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)	6

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:40:47

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)	6
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>	<b>True</b>

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:40:47

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)	6
Date of submission (Pre-filled from custom function)	26/AUG/2020 09:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:40:47

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)	6
Date of submission (Pre-filled from custom function)	16/OCT/2020 12:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 08:40:47

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)	6
Date of submission (Pre-filled from custom function)	19/OCT/2020 15:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 08:40:47

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)	6
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>	<b>True</b>

US3022031

Folder: SAE USA-US051-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 08:40:47

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)	6
Date of submission (Pre-filled from custom function)	17/NOV/2020 08:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3022031 (Prod: Meridian Clinical Research)

**US3022031**

**Form: Participant Creation**

**Generated On: 26 Nov 2020 08:40:47**

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3022031'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	27 Jul 2020 21:14:05

US3022031

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:40:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:12

**US3022031**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:40:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	27 Jul 2020 21:14:06

US3022031

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:12

**US3022031**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:40:47**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	27 Jul 2020 23:42:12



US3022031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:47

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	27 Jul 2020 21:14:07

**US3022031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:40:47**

[Age](#)

Audit	User	Time (GMT)
User entered '66'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

**US3022031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:40:47**

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	27 Jul 2020 23:42:50

**US3022031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:40:47**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '66'	System	27 Jul 2020 23:43:09

**US3022031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:40:47**

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:47

[Ethnicity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[White](#)

Audit	User	Time (GMT)
User entered 'I'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

**US3022031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:40:47**

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50



**US3022031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:40:47**

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:47

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:40:47

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

**US3022031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:40:47**

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

**US3022031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:40:47**

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

**US3022031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:40:47**

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

**US3022031**

**Folder: Screening**

**Form: Demographics**

**Generated On: 26 Nov 2020 08:40:47**

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:42:50

US3022031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:47

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:09



**US3022031**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:40:47**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	27 Jul 2020 23:43:09

**US3022031**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:40:47**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	27 Jul 2020 23:43:09

**US3022031**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:40:47**

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:09

**US3022031**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:40:47**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:09

**US3022031**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:40:47**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:09

US3022031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:47

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:09

US3022031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:47

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:09

US3022031

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:40:47

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	27 Jul 2020 21:14:06



**US3022031**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 26 Nov 2020 08:40:47**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jul 2020 23:43:16

**US3022031**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 26 Nov 2020 08:40:47**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:06:22

US3022031

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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, HLT: 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: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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

**US3022031**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 00:06:33

**US3022031**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 00:06:33

US3022031

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:56:10
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	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: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 00:06:43

**US3022031**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 00:06:43

US3022031

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Limb operation, LLT: Leg operation - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	28 Jul 2020 00:06:59



**US3022031**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1976'	System	28 Jul 2020 00:06:59

**US3022031**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1976'	System	28 Jul 2020 00:06:59

**US3022031**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1976'	System	28 Jul 2020 00:06:59



**US3022031**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1976'	System	28 Jul 2020 00:06:59

US3022031

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:56:48
User coded data point as SOC: Surgical and medical procedures, HLGT: 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: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	28 Jul 2020 00:07:49



**US3022031**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1981'	System	28 Jul 2020 00:07:49

**US3022031**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	28 Jul 2020 00:07:49

**US3022031**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1981'	System	28 Jul 2020 00:07:49

US3022031

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:04:28
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: 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: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	28 Jul 2020 00:08:01

**US3022031**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1981'	System	28 Jul 2020 00:08:01

**US3022031**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	28 Jul 2020 00:08:01

**US3022031**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1981'	System	28 Jul 2020 00:08:01

US3022031

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:04:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: 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: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:04:48
User entered 'UN UNK 2012'	Shanice Bennett (b) (4)	05 Aug 2020 20:40:45
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:04:51
User entered '0'	Shanice Bennett (b) (4)	05 Aug 2020 20:40:45
	(b) (4)	



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**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:04:53
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	05 Aug 2020 20:40:45
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:04:55
User entered empty.	Shanice Bennett (b) (4)	05 Aug 2020 20:40:45
	(b) (4)	

**US3022031**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:04:58
User entered '0'	Shanice Bennett (b) (4)	05 Aug 2020 20:40:45
	(b) (4)	

**US3022031**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	05 Aug 2020 20:40:45

**US3022031**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2012'	System	05 Aug 2020 20:40:45

**US3022031**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:40:45

**US3022031**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:40:45

US3022031

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
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, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\\23.0.	Coder Import (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)	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)	30 Sep 2020 19:00:22
	(b) (4)	



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**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1991'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:00:22

**US3022031**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:00:22

**US3022031**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:00:22

**US3022031**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1991'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:00:22

**US3022031**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:00:22

**US3022031**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	30 Sep 2020 19:00:22

**US3022031**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1991'	System	30 Sep 2020 19:00:22

**US3022031**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	30 Sep 2020 19:00:22



**US3022031**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1991'	System	30 Sep 2020 19:00:22

US3022031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:05:28
User coded data point as SOC: Psychiatric disorders, HLGT: Schizophrenia and other psychotic disorders, HLT: Schizoaffective and schizophreniform disorders, PT: Schizoaffective disorder, LLT: Schizoaffective disorder - version MedDRA\\23.0.	Coder Import (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)	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)	30 Sep 2020 19:05:00
	(b) (4)	

US3022031

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:40:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 19:05:00

**US3022031**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 19:05:00

US3022031

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:06:08
User coded data point as SOC: Psychiatric disorders, HLGT: 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: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	11 Nov 2020 16:40:14

**US3022031**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2007'	System	11 Nov 2020 16:40:14

**US3022031**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:40:14

**US3022031**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:40:14

US3022031

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 18:33:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 18:33:46
Data point term sent to Coder	System	16 Nov 2020 18:33:11
User entered 'muscle spasms'	(b) (4), (b) (6) (b) (4)	16 Nov 2020 18:32:32

**US3022031**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	16 Nov 2020 18:32:32
User entered '30 Sep 2020'	(b) (4), (b) (6)	16 Nov 2020 18:32:32

**US3022031**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:32:32



**US3022031**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 18:32:32

**US3022031**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:32:32

**US3022031**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:32:32

**US3022031**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	16 Nov 2020 18:32:32

**US3022031**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	16 Nov 2020 18:32:32

**US3022031**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:32:32

**US3022031**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:32:32

US3022031

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, 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: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2007'	(b) (4), (b) (6)	16 Nov 2020 18:33:02

**US3022031**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:33:02

**US3022031**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 18:33:02

**US3022031**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:33:02

**US3022031**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:33:02

**US3022031**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	16 Nov 2020 18:33:02

**US3022031**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2007'	System	16 Nov 2020 18:33:02

**US3022031**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:33:02



**US3022031**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:33:02

US3022031

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Immunology and allergy investigations, HLT: Autoimmunity analyses, PT: Antiphospholipid antibodies positive, LLT: Lupus anticoagulant positive - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	16 Nov 2020 18:33:34

**US3022031**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1991'	(b) (4), (b) (6)	16 Nov 2020 18:33:34

**US3022031**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:33:34

**US3022031**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 18:33:34

**US3022031**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:33:34

**US3022031**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:33:34

**US3022031**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	16 Nov 2020 18:33:34



**US3022031**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1991'	System	16 Nov 2020 18:33:34

**US3022031**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:33:34

**US3022031**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:33:34

US3022031

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	16 Nov 2020 18:33:55

**US3022031**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1991'	(b) (4), (b) (6)	16 Nov 2020 18:33:55

**US3022031**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:33:55

**US3022031**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 18:33:55

**US3022031**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:33:55



**US3022031**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:33:55

**US3022031**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	16 Nov 2020 18:33:55

**US3022031**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1991'	System	16 Nov 2020 18:33:55

**US3022031**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:33:55

**US3022031**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:33:55

US3022031

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 08:40:47

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, 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: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1991'	(b) (4), (b) (6)	16 Nov 2020 18:34:12

**US3022031**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:34:12



**US3022031**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 18:34:12

**US3022031**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1992'	(b) (4), (b) (6)	16 Nov 2020 18:34:12

**US3022031**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:34:12

**US3022031**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	16 Nov 2020 18:34:12

**US3022031**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1991'	System	16 Nov 2020 18:34:12

**US3022031**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	16 Nov 2020 18:34:12

**US3022031**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1992'	System	16 Nov 2020 18:34:12

US3022031

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 08:40:47

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	23 Nov 2020 18:01:25
User entered 'Pulmonary embolism' reason for change: Per Query Resolution	Morgan Deal (b) (4) (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) (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) (b) (4)	16 Nov 2020 18:34:28



**US3022031**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1991'	(b) (4), (b) (6)	16 Nov 2020 18:34:28

**US3022031**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:34:28

**US3022031**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 18:34:28

**US3022031**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1991'	(b) (4), (b) (6)	16 Nov 2020 18:34:28

**US3022031**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:34:28

**US3022031**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	16 Nov 2020 18:34:28

**US3022031**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1991'	System	16 Nov 2020 18:34:28

**US3022031**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1991'	System	16 Nov 2020 18:34:28



**US3022031**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1991'	System	16 Nov 2020 18:34:28

US3022031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Overdoses and underdoses NEC, HLT: Overdoses NEC, PT: Overdose, LLT: Drug overdose - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 18:35:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 18:35:46
Data point term sent to Coder	System	16 Nov 2020 18:35:13
User entered 'drug overdose'	(b) (4), (b) (6) (b) (4)	16 Nov 2020 18:34:51

**US3022031**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	16 Nov 2020 18:34:51
User entered '08 Aug 2020'	(b) (4), (b) (6)	16 Nov 2020 18:34:51

**US3022031**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:34:51

**US3022031**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 18:34:51

US3022031

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 08:40:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	23 Nov 2020 17:56:55
User entered '19 Aug 2020' reason for change: Per Query Resolution	Morgan Deal (b) (4)	23 Nov 2020 17:56:55
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	23 Nov 2020 17:55:34
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	23 Nov 2020 17:55:34
User entered 'UN Aug 2020' reason for change: Per Query Resolution	Morgan Deal (b) (4)	23 Nov 2020 17:55:34
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	16 Nov 2020 18:34:51
User entered 'un Jul 2020'	(b) (4), (b) (6)	16 Nov 2020 18:34:51

**US3022031**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:34:51

**US3022031**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	16 Nov 2020 18:34:51



**US3022031**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	16 Nov 2020 18:34:51

**US3022031**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	23 Nov 2020 17:55:34
User entered 'Jul 2020'	System	16 Nov 2020 18:34:51

**US3022031**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	16 Nov 2020 18:34:51

US3022031

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: 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: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2007'	(b) (4), (b) (6)	16 Nov 2020 18:35:03

**US3022031**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:35:03

**US3022031**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 18:35:03

**US3022031**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:35:03



**US3022031**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:35:03

**US3022031**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	16 Nov 2020 18:35:03

**US3022031**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2007'	System	16 Nov 2020 18:35:03

**US3022031**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:35:03

**US3022031**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:35:03

US3022031

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 08:40:47

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Road traffic accident - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	16 Nov 2020 18:35:27

**US3022031**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2007'	(b) (4), (b) (6)	16 Nov 2020 18:35:27

**US3022031**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:35:27



**US3022031**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 08:40:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 18:35:27

**US3022031**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 08:40:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2007'	(b) (4), (b) (6)	16 Nov 2020 18:35:27

**US3022031**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 18:35:27

**US3022031**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	16 Nov 2020 18:35:27

**US3022031**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 08:40:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2007'	System	16 Nov 2020 18:35:27

**US3022031**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	16 Nov 2020 18:35:27

**US3022031**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 26 Nov 2020 08:40:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2007'	System	16 Nov 2020 18:35:27

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:57



**US3022031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Jul 2020'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:57

**US3022031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

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

Audit	User	Time (GMT)
User entered '17:25'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:57

**US3022031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Jul 2020 17:25'	System	28 Jul 2020 00:08:57

**US3022031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '188' cm	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: 26 Nov 2020 08:40:47

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '88.6' kg	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: 26 Nov 2020 08:40:47**

**BMI (xxx.x)**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

Temperature (xxx.x)

Audit	User	Time (GMT)
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) (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)	03 Nov 2020 15:16:15
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (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: 26 Nov 2020 08:40:47**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:16:08
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	28 Jul 2020 00:08:57

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:47

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:08:57

**US3022031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:16:08
User entered '75'	Stella Yoon (b) (4)	28 Jul 2020 00:08:57

**US3022031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Jul 2020 00:08:57

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:16:08
User entered '14'	Stella Yoon (b) (4)	28 Jul 2020 00:08:57

**US3022031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Jul 2020 00:08:57

US3022031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:16:08
User entered '123'	Stella Yoon (b) (4)	28 Jul 2020 00:08:57

**US3022031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Jul 2020 00:08:57



US3022031

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:16:08
User entered '72'	Stella Yoon (b) (4)	28 Jul 2020 00:08:57

**US3022031**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Jul 2020 00:08:57

US3022031

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:47

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:01

**US3022031**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 26 Nov 2020 08:40:47**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User entered '27 Jul 2020'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:01

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34



US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34



US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

[Specify](#)

Audit	User	Time (GMT)
User entered 'in sociAL settings at restaurants and shopping multiple days a week'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

**US3022031**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 26 Nov 2020 08:40:47**

**No Risk Identified**

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

[Other](#)

Audit	User	Time (GMT)
User entered 'I'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34



US3022031

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:40:47

[Specify](#)

Audit	User	Time (GMT)
User entered 'Resident in a community with ongoing person to person transmission'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:34

US3022031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:40:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 08:40:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '27 Jul 2020'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:41

US3022031

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:41

**US3022031**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:40:47**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	28 Jul 2020 00:09:41

US3022031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:47

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	27 Jul 2020 22:19:08

US3022031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:47

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	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) [REDACTED]	27 Jul 2020 22:19:08

US3022031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:47

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	27 Jul 2020 22:19:08



**US3022031**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 08:40:47**

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:52

**US3022031**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 26 Nov 2020 08:40:47**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:52

US3022031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:47

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:52

US3022031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:47

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:52

US3022031

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:40:47

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:09:52

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:47

Height

Audit	User	Time (GMT)
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) (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)	03 Nov 2020 15:15:24
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (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)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:47

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:15:17
User entered '88.6' kg	Stella Yoon (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:47

Height

Audit	User	Time (GMT)
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) (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)	03 Nov 2020 15:15:24
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (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)	28 Jul 2020 00:10:59



US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:47

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:15:17
User entered '88.6' kg	Stella Yoon (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:47

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 08:40:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Jul 2020'	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: 26 Nov 2020 08:40:47**

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

Audit	User	Time (GMT)
User entered '17:25'	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: 26 Nov 2020 08:40:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	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: 26 Nov 2020 08:40:47

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 08:40:47

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 08:40:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '75'	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: 26 Nov 2020 08:40:47**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	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: 26 Nov 2020 08:40:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '123'	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: 26 Nov 2020 08:40:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	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: 26 Nov 2020 08:40:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:47

Height

Audit	User	Time (GMT)
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) (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)	03 Nov 2020 15:15:24
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (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)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:40:47

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	03 Nov 2020 15:15:17
User entered '88.6' kg	Stella Yoon (b) (4)	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:47

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 08:40:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Jul 2020'	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: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	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).	Stella Yoon (b) (4)	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).	(b) (4)	28 Jul 2020 00:10:59
User entered '19:58'	Stella Yoon (b) (4)	28 Jul 2020 00:10:59

**US3022031**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:40:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.2' C	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: 26 Nov 2020 08:40:47

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 08:40:47

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 08:40:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	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: 26 Nov 2020 08:40:47**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 08:40:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	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: 26 Nov 2020 08:40:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	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: 26 Nov 2020 08:40:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Jul 2020 00:10:59

US3022031

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:47

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:18

US3022031

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Jul 2020'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:18

US3022031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

If No, reason not given

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	27 Jul 2020 23:43:52

US3022031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Jul 2020'	Shanice Bennett (b) (4) (b) (4)	27 Jul 2020 23:43:52

US3022031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Jul 2020 19:11'	System	27 Jul 2020 23:43:52

US3022031

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:40:47

Which arm was used to give treatment?

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	27 Jul 2020 23:43:52

**US3022031**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:40:47**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	27 Jul 2020 23:43:52

US3022031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:45



US3022031

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Jul 2020'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:45

**US3022031**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:40:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '18:05'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:45

**US3022031**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:40:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
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), (b) (6)	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: 26 Nov 2020 08:40:47**

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 08:40:47**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered '17:57'	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: 26 Nov 2020 08:40:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 08:40:47**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 08:40:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Jul 2020 00:12:53

US3022031

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:40:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	28 Jul 2020 00:12:56

**US3022031**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:40:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Jul 2020 00:12:56

**US3022031**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	13 Aug 2020 15:28:38
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 20:39:58
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	29 Jul 2020 12:34:32
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: 26 Nov 2020 08:40:47**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
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).	(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: 26 Nov 2020 08:40:47**

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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' User entered '0'	System	01 Aug 2020 02:52:11

**US3022031**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 26 Nov 2020 08:40:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
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-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: 26 Nov 2020 08:40:47**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**HEADACHE**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**FATIGUE**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**CHILLS**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	27 Jul 2020 23:55:05
User entered '27 Jul 2020 19:55'	System	27 Jul 2020 23:55:05



**US3022031**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**HEADACHE**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**FATIGUE**

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 08:40:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 08:40:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**CHILLS**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	29 Jul 2020 12:36:19
User entered '29 Jul 2020 08:36'	System	29 Jul 2020 12:36:19

**US3022031**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**HEADACHE**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**FATIGUE**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**CHILLS**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**HEADACHE**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**FATIGUE**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**CHILLS**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	25 Aug 2020 19:00:33

**US3022031**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:40:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Aug 2020 19:00:37

US3022031

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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)	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)	25 Aug 2020 19:00:53

**US3022031**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:40:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User closed query 'The Contact Status is 'CONTACT System NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).		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	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: 26 Nov 2020 08:40:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
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) (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)	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: 26 Nov 2020 08:40:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Aug 2020 19:02:00

**US3022031**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:40:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:29:36

US3022031

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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.'	(b) (4), (b) (6)	11 Nov 2020 16:29:51
answered with 'THIS IS CORRECT' (Site from System).		
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: 26 Nov 2020 08:40:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	11 Nov 2020 16:29:36

**US3022031**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:40:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered 'VM LEFT NUMEROUS TIMES'	(b) (4), (b) (6)	11 Nov 2020 16:29:36

US3022031

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:29:41



**US3022031**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:40:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 16:29:41

**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:40:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:30:03

US3022031

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:40:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	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: 26 Nov 2020 08:40:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Nov 2020 16:30:03

**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:40:47**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	11 Nov 2020 16:30:03

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:47

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 16:30:33



US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
User entered '13:36'	(b) (4), (b) (6)	11 Nov 2020 16:30:33

**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:47

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:47

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '82'	(b) (4), (b) (6)	11 Nov 2020 16:30:33

**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '15'	(b) (4), (b) (6)	11 Nov 2020 16:30:33



**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	(b) (4), (b) (6)	11 Nov 2020 16:30:33

**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:40:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	11 Nov 2020 16:30:33

**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Nov 2020 16:30:33

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:47

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

Were vital signs assessed?

Audit	User	Time (GMT)
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) (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)	19 Nov 2020 20:35:11
User entered 'No (N)' reason for change: Data Entry Error	(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)	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

US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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



US3022031

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:40:47

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Post-dose Time is prior to Pre-dose Time. 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 '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: 26 Nov 2020 08:40:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	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: 26 Nov 2020 08:40:47**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	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: 26 Nov 2020 08:40:47**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:22:25

**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 26 Nov 2020 08:40:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	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: 26 Nov 2020 08:40:47**

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	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: 26 Nov 2020 08:40:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	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: 26 Nov 2020 08:40:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	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: 26 Nov 2020 08:40:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:30:49

US3022031

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 16:30:49

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 16:31:40



US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:47

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4), (b) (6)	11 Nov 2020 16:31:40

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:47

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

Audit	User	Time (GMT)
User entered 'DUE TO OVERDOSE OF MED'	(b) (4), (b) (6)	11 Nov 2020 16:31:40

**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:40:47**

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:31:40

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:31:40

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:31:40

**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:40:47**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:31:40

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:47

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:31:40

US3022031

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:40:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:31:40



**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 26 Nov 2020 08:40:47**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:31:40

US3022031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:32:01

US3022031

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	11 Nov 2020 16:32:01

**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:40:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:09'	(b) (4), (b) (6)	11 Nov 2020 16:32:01

**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:40:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(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: 26 Nov 2020 08:40:47**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered '13:58'	(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: 26 Nov 2020 08:40:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 08:40:47**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 08:40:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:32:13

US3022031

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:32:30

**US3022031**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:40:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 16:32:30



US3022031

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:34:08

**US3022031**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:40:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (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: 26 Nov 2020 08:40:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 21:31:33
User entered 'SUBJECT NOT CALLED DUE TO NOT RECIEVING VAX 2'	(b) (4), (b) (6)	11 Nov 2020 16:34:08

US3022031

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:59:32

**US3022031**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:40:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 16:59:32

US3022031

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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 21:31:51
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) [REDACTED]	11 Nov 2020 16:59:44

**US3022031**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:40:47**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 16:59:44



**US3022031**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:40:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (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: 26 Nov 2020 08:40:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 21:31:51
User entered 'CONTACT NOT MADE'	(b) (4), (b) (6)	11 Nov 2020 16:59:44

US3022031

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:40:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 16:59:49

**US3022031**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:40:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 16:59:49

US3022031

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:40:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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 21:32:07
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: 26 Nov 2020 08:40:47**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 17:00:03

**US3022031**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 26 Nov 2020 08:40:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (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: 26 Nov 2020 08:40:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 21:32:07
User entered 'CONTACT NOT MADE'	(b) (4), (b) (6)	11 Nov 2020 17:00:03



**US3022031**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:40:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 17:00:07

**US3022031**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:40:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 17:00:07

**US3022031**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:40:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 17:00:18

**US3022031**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:40:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	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: 26 Nov 2020 08:40:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Nov 2020 17:00:18

**US3022031**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 26 Nov 2020 08:40:47**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	11 Nov 2020 17:00:18

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

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

Audit	User	Time (GMT)
User entered '14:00'	(b) (4), (b) (6)	11 Nov 2020 17:00:43

**US3022031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	11 Nov 2020 17:00:43

**US3022031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Nov 2020 17:00:43

**US3022031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 17:00:43

**US3022031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	(b) (4), (b) (6)	11 Nov 2020 17:00:43

**US3022031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	11 Nov 2020 17:00:43



**US3022031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '117'	(b) (4), (b) (6)	11 Nov 2020 17:00:43

**US3022031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:40:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '70'	(b) (4), (b) (6)	11 Nov 2020 17:00:43

**US3022031**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 26 Nov 2020 08:40:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Nov 2020 17:00:43

US3022031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 17:00:52

US3022031

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:40:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
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
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) (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), (b) (6)	13 Nov 2020 05:27:48



US3022031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 17:01:11

US3022031

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:40:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:24'	(b) (4), (b) (6)	11 Nov 2020 17:01:11

**US3022031**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 26 Nov 2020 08:40:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 17:01:15

**US3022031**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 26 Nov 2020 08:40:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 17:01:15

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[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: '2020-09-27T18:01:29', 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: 26 Nov 2020 08:40:47**

Have you been exposed to someone with 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: '2020-09-27T18:02:34', 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: 26 Nov 2020 08:40:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[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: '2020-10-03T19:46:25', 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: 26 Nov 2020 08:40:47**

[Have you been exposed to someone with 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: '2020-10-03T19:46:43', 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: 26 Nov 2020 08:40:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
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'	System	03 Oct 2020 23:46:59
User entered '03 Oct 2020 19:46:54'	System	03 Oct 2020 23:46:59



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[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: '2020-10-10T14:35:15', 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: 26 Nov 2020 08:40:47**

Have you been exposed to someone with 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: '2020-10-10T14:35:26', 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: 26 Nov 2020 08:40:47**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 08:40:47**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 08:40:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[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: '2020-10-26T07:47:02', 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: 26 Nov 2020 08:40:47**

Have you been exposed to someone with 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: '2020-10-26T07:46:48', 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: 26 Nov 2020 08:40:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[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: '2020-10-31T17:23:48', 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: 26 Nov 2020 08:40:47**

Have you been exposed to someone with 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: '2020-10-31T17:23:55', 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: 26 Nov 2020 08:40:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 02:15:21

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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 Sep 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: 26 Nov 2020 08:40:47**

[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 Sep 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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 02:15:21

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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 Sep 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: 26 Nov 2020 08:40:47**

[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 Oct 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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 02:15:21

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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 Oct 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: 26 Nov 2020 08:40:47**

[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 Oct 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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 02:15:21



**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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 Oct 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: 26 Nov 2020 08:40:47**

[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 Oct 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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 02:15:21

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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 Oct 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: 26 Nov 2020 08:40:47**

[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 Oct 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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 02:15:21

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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 Oct 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: 26 Nov 2020 08:40:47**

[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 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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 02:15:21

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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 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: 26 Nov 2020 08:40:47**

[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 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: 26 Nov 2020 08:40:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:15:21
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 02:15:21

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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 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: 26 Nov 2020 08:40:47**

[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 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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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

**US3022031**

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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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



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

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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)**

**Form: Safety Follow Up Diary**

**Generated On: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

**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: 26 Nov 2020 08:40:47**

[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: 26 Nov 2020 08:40:47**

[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: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 26 Nov 2020 08:40:47**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:35:10
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	25 Aug 2020 18:55:21
	(b) (4)	

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:47

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Overdoses and underdoses NEC, HLT: Overdoses NEC, PT: Overdose, LLT: Drug overdose - version MedDRA\23.0.	Coder Import (b) (4) (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) (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) (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) (b) (4)	30 Sep 2020 19:46:19
User entered 'overdose of benzodiazepine' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	30 Sep 2020 19:46:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Myopathies, PT: Rhabdomyolysis, LLT: Rhabdomyolysis - version MedDRA\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	25 Aug 2020 18:57:11

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	30 Sep 2020 19:44:31
User entered 'No (N)' reason for change: Data Entry Error	(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)	25 Aug 2020 18:57:11

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'No (N)'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11
	(b) (4)	

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '10 Aug 2020'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11
	(b) (4)	

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11
	(b) (4)	

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:57:11

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'No (N)'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '19 Aug 2020'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11
	(b) (4)	

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11
	(b) (4)	



**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 18:57:11

US3022031

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:47

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11
	(b) (4)	

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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).		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 18:58:32
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'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	25 Aug 2020 18:58:53
User entered empty.	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11
	(b) (4)	

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11
	(b) (4)	

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	26 Aug 2020 12:39:09
User entered 'Related (RELATED)'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(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 hopsital' (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: 26 Nov 2020 08:40:47

None

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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 'I'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered '0'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
User entered empty.	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:47

[Narrative](#)

Audit	User	Time (GMT)
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
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)	13 Nov 2020 22:48:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
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)	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)	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
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:40:47

[Narrative](#)

Audit	User	Time (GMT)
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
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.' answered with 'will update' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 16:38:46



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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
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 'will update' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 16:38:36
Query 'PV query: Per query response hyperlipidemia started in 2019 but EDC shows that it started in 2020. Please clarify' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:06:57
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.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:06:14
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.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 13:06:07
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.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 13:45:46
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

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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 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
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)	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)	30 Sep 2020 19:45:42

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
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)	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)	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)	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)	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
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

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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: 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
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).	System	25 Aug 2020 18:57:11
User entered empty.	Shanice Bennett (b) (4)	25 Aug 2020 18:57:11

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Aug 2020 18:57:11

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Aug 2020 18:57:11

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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: 26 Nov 2020 08:40:47**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)

Generated On: 26 Nov 2020 08:40:47

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Pulmonary failure - version MedDRA\\23.0.	Coder Import (b) (4) (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.	Coder Import (b) (4) (b) (4)	12 Nov 2020 19:16:34
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:46:29

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:40:47**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:46:29

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:40:47**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:49:55
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:14:02
User entered 'Not Related (NOT RELATED)'	(b) (4)	
reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:14:02
DataPoint Verified.	(b) (4)	
	(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: 26 Nov 2020 08:40:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:49:58
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:14:02
User entered 'Not Related (NOT RELATED)'	(b) (4)	
reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:14:02
DataPoint Verified.	(b) (4)	
	(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: 26 Nov 2020 08:40:47

Action taken with investigational product

Audit	User	Time (GMT)
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)	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: 26 Nov 2020 08:40:47**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:51:24
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:19:06
User entered '0' reason for change: Data Entry Error	(b) (4)	
	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: 26 Nov 2020 08:40:47**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:51:30
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:19:06
User entered '1' reason for change: Data Entry Error	(b) (4)	16 Nov 2020 18:19:06
DataPoint Verified.	Shanice Bennett (b) (4)	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: 26 Nov 2020 08:40:47**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:51:33
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:14:02
User entered 'klonapin overdose' reason for change:	(b) (4)	
Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:14:02
DataPoint Verified.	(b) (4)	
	(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:	(b) (4), (b) (6)	11 Nov 2020 16:46:55
Data Entry Error		
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: 26 Nov 2020 08:40:47**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 16:46:29

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:40:47**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 16:46:29

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 26 Nov 2020 08:40:47**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 16:46:29

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:40:47**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:33:42
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) (b) (4)	11 Nov 2020 17:04:33
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 17:04:33
Data point term sent to Coder	System	11 Nov 2020 16:48:40
User entered 'PNUEMONIA'	(b) (4), (b) (6)	11 Nov 2020 16:48:06

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:48:06

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 16:48:06

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:52:03
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:15:37
User entered 'Not Related (NOT RELATED)'	(b) (4)	
reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:15:37
DataPoint Verified.	(b) (4)	
	(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: 26 Nov 2020 08:40:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:52:05
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:15:37
User entered 'Not Related (NOT RELATED)'	(b) (4)	
reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:15:37
DataPoint Verified.	(b) (4)	
	(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: 26 Nov 2020 08:40:47**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
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 16:48:06

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:40:47**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:52:12
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:19:47
User entered '0' reason for change: Data Entry Error	(b) (4)	
	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

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:52:14
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:19:47
User entered '1' reason for change: Data Entry Error	(b) (4)	16 Nov 2020 18:19:47
DataPoint Verified.	Shanice Bennett (b) (4)	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: 26 Nov 2020 08:40:47**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:40:47**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:52:18
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:15:37
User entered 'SAE Due to Klonapin overdose'	(b) (4)	
reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:15:37
DataPoint Verified.	(b) (4)	
	(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: 26 Nov 2020 08:40:47**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 16:48:06

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 16:48:06

**US3022031**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 16:48:06

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:40:47

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Please add klonopin and fluoxetine per ConMed log.' (Site from CRA).	(b) (4), (b) (6)	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
	(b) (4)	



US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:40:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:25:32
	(b) (4)	
User entered '40' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Nov 2020 18:25:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:40:56
User entered '10'	Stella Yoon (b) (4)	28 Jul 2020 00:13:28
	(b) (4)	

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (b) (4)	22 Sep 2020 19:08:41
User entered 'UN UNK 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (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) (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
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: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	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) (b) (4)	28 Jul 2020 00:13:28

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:40:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
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) (b) (4)	28 Jul 2020 00:13:28

US3022031

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	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: 26 Nov 2020 08:40:47**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jul 2020 00:13:51

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:40:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jul 2020 00:13:51

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 26 Nov 2020 08:40:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Jul 2020 00:13:51

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:36
User entered 'No (N)'	Shanice Bennett (b) (4)	05 Aug 2020 20:42:09
	(b) (4)	

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:37
User entered 'BACK PAIN'	Shanice Bennett (b) (4)	05 Aug 2020 20:42:09
	(b) (4)	

US3022031

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:39
User entered '10/325'	Shanice Bennett (b) (4)	05 Aug 2020 20:42:09
	(b) (4)	



**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:41
User entered 'mg (mg)'	Shanice Bennett (b) (4)	05 Aug 2020 20:42:09
	(b) (4)	

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:40:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:46
User entered empty.	Shanice Bennett (b) (4)	05 Aug 2020 20:42:09
	(b) (4)	

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:47
User entered 'as needed (PRN)'	Shanice Bennett (b) (4)	05 Aug 2020 20:42:09
	(b) (4)	

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:47

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:49
User entered empty.	Shanice Bennett (b) (4)	05 Aug 2020 20:42:09
	(b) (4)	

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:51
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	05 Aug 2020 20:42:09
	(b) (4)	

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:40:47**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:44:53
User entered empty.	Shanice Bennett (b) (4)	05 Aug 2020 20:42:09
	(b) (4)	

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:40:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	05 Aug 2020 20:42:09

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:01
User entered '0'	Shanice Bennett (b) (4)	05 Aug 2020 20:42:09
	(b) (4)	



**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:04
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	05 Aug 2020 20:42:09
	(b) (4)	

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:40:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:06
User entered empty.	Shanice Bennett (b) (4)	05 Aug 2020 20:42:09
	(b) (4)	

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:08
User entered 'No (N)'	Shanice Bennett (b) (4)	05 Aug 2020 20:42:09
	(b) (4)	

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:42:09

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:42:09

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:42:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:40:47

Name of Medication

Audit	User	Time (GMT)
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) (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) (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	System	16 Nov 2020 18:25:56
Coding entries removed.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:25:00
User entered 'Aopiprazole' reason for change: Data Entry Error	Shanice Bennett (b) (4) (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) (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) (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) (b) (4)	30 Sep 2020 19:02:22

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 08:40:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Dose per administration](#)

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 08:40:47**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (6)	25 Nov 2020 05:24:06
User entered '17 Aug 2020' reason for change: Data Entry Error 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). User entered 'un UNK 2007' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4) Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 15:48:01 16 Nov 2020 18:25:00 13 Nov 2020 22:55:51
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). User closed query 'Per DM CLR: Con Med ARIPIRAZOLE 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).	Shanice Bennett (b) (4) (b) (4) (b) (4), (b) (6)	13 Nov 2020 22:55:45 13 Nov 2020 05:09:38
	(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: 26 Nov 2020 08:40:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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. ' 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. ' (Site from DM). User entered '9 Sep 2020'	(b) (4), (b) (6) (b) (4) (b) (4), (b) (6) (b) (4) Stella Yoon (b) (4) (b) (4)	11 Nov 2020 16:41:30    03 Nov 2020 20:41:30    30 Sep 2020 19:02:22

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 19:02:22

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 08:40:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 19:02:22



**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 26 Nov 2020 08:40:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 19:02:22

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 08:40:47

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	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) (b) (4)	17 Nov 2020 06:38:55
Data point term sent to Coder DataPoint Un-verified.	System (b) (4), (b) (6)	12 Nov 2020 22:26:35 12 Nov 2020 22:26:27
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 Coding entries removed.	System (b) (4), (b) (6)	11 Nov 2020 16:43:28 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 User entered 'duloxetine'	System Stella Yoon (b) (4) (b) (4)	30 Sep 2020 19:04:49 30 Sep 2020 19:04:18

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 08:40:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

[Indication](#)

Audit	User	Time (GMT)
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
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: 26 Nov 2020 08:40:47**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (b) (4)	30 Sep 2020 19:04:18

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	16 Nov 2020 18:27:53
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:27:53
Coding entries removed.	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:27:53
User entered 'Rivaroxaban' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Nov 2020 18:27:53
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	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) (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) (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) (b) (4)	11 Nov 2020 16:44:09

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 08:40:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:27:53
	(b) (4)	
User entered 'Hypercoagulable stables' 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 14:40:11
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: 26 Nov 2020 08:40:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	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
User entered '40'	(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: 26 Nov 2020 08:40:47**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Shanice Bennett (b) (4)	16 Nov 2020 18:27:53
	(b) (4)	
User entered 'UN UNK 1991' reason for change:	Shanice Bennett (b) (4)	16 Nov 2020 18:27:53
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:40:31
	(b) (4), (b) (6)	
User entered '17 Aug 2020'	(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: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 16:44:09

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 08:40:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 16:44:09

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 26 Nov 2020 08:40:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 16:44:09

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 08:40:47

[Name of Medication](#)

Audit	User	Time (GMT)
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)	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) (b) (4)	12 Nov 2020 22:28:16

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 08:40:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 08:40:47

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	(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: 26 Nov 2020 08:40:47

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(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: 26 Nov 2020 08:40:47**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 08:40:47**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(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: 26 Nov 2020 08:40:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 08:40:47**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(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: 26 Nov 2020 08:40:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	(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: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(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: 26 Nov 2020 08:40:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(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: 26 Nov 2020 08:40:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 08:40:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 08:40:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 22:28:16

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 08:40:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 22:28:16

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 26 Nov 2020 08:40:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 22:28:16

US3022031

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 08:40:47

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 08:40:47**

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(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: 26 Nov 2020 08:40:47**

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(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: 26 Nov 2020 08:40:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 08:40:47**

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(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: 26 Nov 2020 08:40:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 08:40:47**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(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: 26 Nov 2020 08:40:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 08:40:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020'	(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: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(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: 26 Nov 2020 08:40:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 08:40:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(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: 26 Nov 2020 08:40:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 08:40:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Name of Medication](#)

Audit	User	Time (GMT)
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.	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: 26 Nov 2020 08:40:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 08:40:47

[Indication](#)

Audit	User	Time (GMT)
User entered 'nightmares'	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: 26 Nov 2020 08:40:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	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: 26 Nov 2020 08:40:47

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	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: 26 Nov 2020 08:40:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 08:40:47

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	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: 26 Nov 2020 08:40:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 08:40:47**

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	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: 26 Nov 2020 08:40:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 08:40:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered 'un Jun 2020'	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: 26 Nov 2020 08:40:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 08:40:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 08:40:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 08:40:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 08:40:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 18:28:50

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 08:40:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 18:28:50

**US3022031**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 26 Nov 2020 08:40:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Nov 2020 18:28:50

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:40:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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	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

**US3022031**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 08:40:47**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered '10 Aug 2020'	Shanice Bennett (b) (4)	16 Nov 2020 18:22:46
	(b) (4)	

US3022031

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered 'CT Scan'	Shanice Bennett (b) (4)	16 Nov 2020 18:22:46
	(b) (4)	

**US3022031**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 08:40:47**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4)	16 Nov 2020 18:22:46
	(b) (4)	

**US3022031**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 26 Nov 2020 08:40:47**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered empty.	Shanice Bennett (b) (4)	16 Nov 2020 18:22:46
	(b) (4)	



US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:40:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered '10 Aug 2020'	Shanice Bennett (b) (4)	16 Nov 2020 18:23:17
	(b) (4)	

**US3022031**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 08:40:47**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered 'Chest Xray'	Shanice Bennett (b) (4)	16 Nov 2020 18:23:17
	(b) (4)	

**US3022031**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 26 Nov 2020 08:40:47**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4)	16 Nov 2020 18:23:17
	(b) (4)	

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:40:47

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered empty.	Shanice Bennett (b) (4)	16 Nov 2020 18:23:17
	(b) (4)	

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 08:40:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered '10 Aug 2020'	Shanice Bennett (b) (4)	16 Nov 2020 18:23:44
	(b) (4)	

**US3022031**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered 'Mechanical Ventilator'	Shanice Bennett (b) (4)	16 Nov 2020 18:23:44

**US3022031**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 26 Nov 2020 08:40:47**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4)	16 Nov 2020 18:23:44
	(b) (4)	

US3022031

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 08:40:47

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 15:48:40
User entered empty.	Shanice Bennett (b) (4)	16 Nov 2020 18:23:44
	(b) (4)	



US3022031

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:40:47

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
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).	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).	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: 26 Nov 2020 08:40:47**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(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 'I'	(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: 26 Nov 2020 08:40:47**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(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 'I'	(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: 26 Nov 2020 08:40:47**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(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 'I'	(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: 26 Nov 2020 08:40:47**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(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 'I'	(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: 26 Nov 2020 08:40:47**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 13:17:08
User entered 'I'	(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: 26 Nov 2020 08:40:47**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 08:40:47**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 08:40:47

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 13:17:18