

US3022291 (Prod: Meridian Clinical Research-Savannah)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:52:28

All time stamps listed in this document are displayed in GMT

US3022291

Form: Participant Creation

Data signed: (b) (4) 24 Feb 2021 00:36:23

Generated On: 09 Jun 2021 14:52:28

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Participant ID

US3022291

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

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US3022291

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

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

US3022291

Folder: Screening

Form: Demographics

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	45
Age Units	YEARS
Age (Derived)	45
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input checked="" type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Date of Informed Consent ( <i>dd MMM yyyy</i> )	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify _____	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number _____	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Condition	RIGHT KNEE OSTEOARTHRITIS
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)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3022291

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JAN 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Condition	GASTRIC BYPASS
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Condition	STOMACH ULCER SURGERY
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Condition	STOMACH ULCER
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Condition	OBESITY
Start date (dd MMM yyyy)	UN (b) (6) 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

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



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	08:09 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 08:09
Height (xxx.x)	171 cm
Weight (xxx.x)	118.2 kg
BMI (xxx.x)	40.42269 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:36:24

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 24 Feb 2021 00:36:24

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Date of assessment (*dd MMM yyyy*) 24 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

If No, what is the reason? Surgically sterile ☐  
Post-menopausal ☐  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_  
If Surgically sterile, date of surgery (*dd MMM yyyy*) \_\_\_\_\_  
Date of surgery unknown False  
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) \_\_\_\_\_  
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 24 Feb 2021 00:36:24

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	24 AUG 2020
Test performed	Urine <input type="radio"/>
	Serum <input checked="" type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 24 Feb 2021 00:36:24

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 144809

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

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

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

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

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

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

Liver Disease Yes ☐   
 No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐   
 No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

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)	24 AUG 2020
Time of assessment (00:00-23:59)	08:09 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 08:09
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	10:50 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 10:50
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 24 AUG 2020

What was the treatment time? (00:00-23:59) 10:17 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 10:17

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 AUG 2020

Collection time (00:00-23:59)

09:12 (24 HR)

Collection date and time (derived)

24 AUG 2020 09:12



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:50	24 AUG 2020 08:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 10:51

PC Open Date & Time

24 AUG 2020 10:37

PC Close Date & Time

24 AUG 2020 13:07

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.1 °F

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

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

PC Time Stamp	25 AUG 2020 09:22
PC Open Date & Time	24 AUG 2020 14:02
PC Close Date & Time	25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**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

97.2 °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

26 AUG 2020 05:29

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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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

97.2 °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 AUG 2020 00:25

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 20:04

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:52:28

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.3 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

29 AUG 2020 07:55

---

PC Open Date & Time

28 AUG 2020 12:00

---

PC Close Date & Time

29 AUG 2020 11:59

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US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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 AUG 2020 08:26

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**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

94.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 22:22

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**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

24 AUG 2020 10:52

PC Open Date & Time

24 AUG 2020 10:37

PC Close Date & Time

24 AUG 2020 13:07

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 09:22

PC Open Date & Time

24 AUG 2020 14:02

PC Close Date & Time

25 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**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

26 AUG 2020 05:29

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**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

27 AUG 2020 00:26

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 20:04

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**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

29 AUG 2020 07:55

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59



US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 08:26

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 22:22

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**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 ☐

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 10:52
PC Open Date & Time	24 AUG 2020 10:37
PC Close Date & Time	24 AUG 2020 13:07

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**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 ☐

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 09:22
PC Open Date & Time	24 AUG 2020 14:02
PC Close Date & Time	25 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**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 ☒

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 05:30
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59



US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 20:04
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

60 of 2067

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 07:55
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**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 ☒

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:52:28

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 08:28
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59



US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**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 ☒

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 22:22
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3022291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022291

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022291

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022291

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3022291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:36:25

Generated On: 09 Jun 2021 14:52:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 00:36:25

Generated On: 09 Jun 2021 14:52:28

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)	28 SEP 2020
Time of assessment (00:00-23:59)	12:46 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 12:46
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 00:36:25

Generated On: 09 Jun 2021 14:52:28

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	15:04 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 15:04
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3022291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:36:25

Generated On: 09 Jun 2021 14:52:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3022291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 24 Feb 2021 00:36:25

Generated On: 09 Jun 2021 14:52:28

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	28 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 00:36:25

Generated On: 09 Jun 2021 14:52:28

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 14:34 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 14:34

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

US3022291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 00:36:25

Generated On: 09 Jun 2021 14:52:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 SEP 2020
Collection time (00:00-23:59)	13:02 (24 HR)
Collection date and time (derived)	28 SEP 2020 13:02

US3022291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 00:36:25

Generated On: 09 Jun 2021 14:52:28

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:24	28 SEP 2020 13:24
Nasopharyngeal Swab 2	No		



US3022291

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:36:25

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**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

97.7 °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

28 SEP 2020 15:02

PC Open Date & Time

28 SEP 2020 14:54

PC Close Date & Time

28 SEP 2020 17:24

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.6 °F

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

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

PC Time Stamp	29 SEP 2020 08:18
PC Open Date & Time	28 SEP 2020 18:19
PC Close Date & Time	29 SEP 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 00:01

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**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

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 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 00:00

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 12:13

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 19:03

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59



US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 09:40

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 15:03

PC Open Date & Time

28 SEP 2020 14:54

PC Close Date & Time

28 SEP 2020 17:24

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 08:18

PC Open Date & Time

28 SEP 2020 18:19

PC Close Date & Time

29 SEP 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**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

30 SEP 2020 00:02

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**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 ☐

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 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 00:00

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**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

02 OCT 2020 12:13

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 19:04

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59



US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**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

05 OCT 2020 09:41

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**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 ☐

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 15:04
PC Open Date & Time	28 SEP 2020 14:54
PC Close Date & Time	28 SEP 2020 17:24

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**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 ☐

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 08:19
PC Open Date & Time	28 SEP 2020 18:19
PC Close Date & Time	29 SEP 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 00:13
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

Yes ☐

PC Time stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

105 of 2067

EAB) (1725)

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

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

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:15
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**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 ☒

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:52:28

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 19:04
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**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 ☒



US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 09:41
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3022291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022291

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022291

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022291

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:36:25

Generated On: 09 Jun 2021 14:52:28

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



US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 00:36:25

Generated On: 09 Jun 2021 14:52:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	08:24 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 08:24
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022291

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:36:25

Generated On: 09 Jun 2021 14:52:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3022291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 00:36:25

Generated On: 09 Jun 2021 14:52:28

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

08:39 (24 HR)

Collection date and time (derived)

23 OCT 2020 08:39

US3022291

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:36:25

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 OCT 2020 00:47:55
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 00:02:11
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 00:02:25

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

18 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 03:49:20
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 00:34:45

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 12:01:47

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 00:01:43

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 09:01:57

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 00:01:37

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 00:16:53

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59



US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 11:06:34

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 00:02:27
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 00:01:58

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 00:07:10
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 01:28:55

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 00:42:00
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 09:58:54

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 08:40:27
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59



US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 04:09:23

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 12:00:32

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 12:06:15

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 12:01:14

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 05:12:21

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 APR 2021 12:00:33
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 00:03:28

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 12:00:56

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59



US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 MAY 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59



US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

23 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

21 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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="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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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



US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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="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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	13 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2021 23:59
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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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



US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

01 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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



US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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="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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 FEB 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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 <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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59



US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 APR 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59



US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JUL 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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="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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	05 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59
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US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

**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 ☐

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 OCT 2022 23:59



US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 OCT 2022 23:59

US3022291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 OCT 2022 23:59

**US3022291**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 09 Jun 2021 14:52:28**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 08:40:51

US3022291

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022291

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3022291

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022291

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

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

US3022291

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3022291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	23 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	15:37 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 15:37
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	69 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022291

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 MAR 2021

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



US3022291

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	15:54 (24 HR)
Collection date and time (derived)	23 MAR 2021 15:54

US3022291

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3022291**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

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*

**US3022291**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022291

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:52:28

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

**US3022291**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 14:52:28**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3022291

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

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3022291

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

Form: Unblinding

Data signed: (b) (4) 25 Mar 2021 23:10:41

Generated On: 09 Jun 2021 14:52:28

Date of updated informed consent ( <i>dd MMM yyyy</i> )	11 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	11 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1



US3022291

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3022291

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	16:35 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 16:35
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)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3022291

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	17:47 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 17:47
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3022291

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

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3022291

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

Form: Pregnancy Test

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	11 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3022291

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

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 FEB 2021

What was the treatment time? (00:00-23:59) 17:07 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 17:07

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

US3022291

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 FEB 2021
Collection time (00:00-23:59)	15:45 (24 HR)
Collection date and time (derived)	11 FEB 2021 15:45

US3022291

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 FEB 2021
Collection time (00:00 - 23:59)	15:40
Collection Date and Time (derived)	11 FEB 2021 15:40



US3022291

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

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022291

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

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

US3022291

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3022291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

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)	23 MAR 2021
Time of assessment (00:00-23:59)	15:37 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 15:37
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3022291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

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)	23 MAR 2021
Time of assessment (00:00-23:59)	17:06 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 17:06
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3022291

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 MAR 2021

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

US3022291

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	23 MAR 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	



US3022291

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 23 MAR 2021

What was the treatment time? (00:00-23:59) 16:36 (24 HR)

Treatment Date and Time (derived) 23 MAR 2021 16:36

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

US3022291

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022291

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 22:24:07

Generated On: 09 Jun 2021 14:52:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022291

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3022291

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	22 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	08:27 (24 HR)
Vital Signs Date and Time (derived)	22 APR 2021 08:27
Temperature ( <i>xxx.x</i> )	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	62 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022291

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 APR 2021

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

US3022291

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 APR 2021
Collection time (00:00-23:59)	08:38 (24 HR)
Collection date and time (derived)	22 APR 2021 08:38



US3022291

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 24 Feb 2021 00:36:23

Generated On: 09 Jun 2021 14:52:28

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Feb 2021 00:36:23

Generated On: 09 Jun 2021 14:52:28

AEID	USA-US051-2020-MRNA-1273-P30 1000013
Adverse event	WORSENING OF RIGHT KNEE ARTHRITIS
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)	09 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 NOV 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)	09 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	12 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Feb 2021 00:36:23

Generated On: 09 Jun 2021 14:52:28

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PRE-PLANNED SURGERY FOR WORSENING FOR RIGHT KNEE ARTHRITIS THAT STARED IN UN/UNK/2019
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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EAB) (1725)

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US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 24 Feb 2021 00:36:23

Generated On: 09 Jun 2021 14:52:28

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

Yes ☒

No ☐

---

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

---

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Name of Medication DICLOFENAC

Prophylaxis Yes ☐  
No ☒

Indication RIGHT KNEE ARTHRITIS

Dose per administration 75-200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

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

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Name of Medication CELECOXIB

Prophylaxis Yes ☐  
No ☒

Indication RIGHT KNEE ARTHRITIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

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



US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Name of Medication OLMESARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

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

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Name of Medication ELIQUIS

Prophylaxis Yes ☐  
No ☒

Indication WORSENING RIGHT KNEE  
ARTHRITIS

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	09 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Name of Medication OXYCODONE/ACETAMINOPHE  
N

Prophylaxis Yes ☐  
No ☒

Indication WORSENING RIGHT KNEE  
OTSTEOARTHRITIS

Dose per administration 10/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	09 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Name of Medication AMBIEN

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

	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)	28 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

Name of Medication FLUOXETINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 11:21:13

Generated On: 09 Jun 2021 14:52:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3022291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3022291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 24 Feb 2021 00:36:23

Generated On: 09 Jun 2021 14:52:28

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
09 NOV 2020	RIGHT KNEE REPLACEMENT	Adverse Event	

US3022291

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:52:28

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3022291

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:52:28

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 ☐

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

SAEID	USA-US051-2020-MRNA-1273-P301000013
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)	2

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

SAEID	USA-US051-2020-MRNA-1273-P301000013
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)	2
Date of submission (Pre-filled from custom function)	24/NOV/2020 01:00
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



US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Feb 2021 00:36:24

Generated On: 09 Jun 2021 14:52:28

SAEID	USA-US051-2020-MRNA-1273-P301000013
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)	2
Date of submission (Pre-filled from custom function)	21/JAN/2021 17:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3022291 (Prod: Meridian Clinical Research-Savannah)

**US3022291**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:52:28**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'US3022291'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 12:19:27

**US3022291**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:24:49
	(b) (4)	

US3022291

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:52:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '24 AUG 2020'	RWS_ENDPOINT	24 Aug 2020 12:19:28
	ENDPOINT (b) (4)	
	(b) (4)	

US3022291

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:52:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Clinic (Clinic)'	Stella Yoon (b) (4)	24 Aug 2020 19:24:49
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
User entered 'SCRN'	(b) (4), (b) (6) System	24 Aug 2020 19:24:49

US3022291

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:52:28

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered (b) (6) 1975'	RWS_ENDPOINT	24 Aug 2020 12:19:29
	ENDPOINT (b) (4)	
	(b) (4)	



**US3022291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:52:28**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '45'	Stella Yoon (b) (4)	24 Aug 2020 19:26:02
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:52:28**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'YEARS'	(b) (4), (b) (6) System	24 Aug 2020 19:26:02

**US3022291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:52:28**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '45'	(b) (4), (b) (6) System	24 Aug 2020 14:48:39

**US3022291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:52:28**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Female (F)'	Stella Yoon (b) (4)	24 Aug 2020 19:26:02
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:52:28**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Not Reported (NOT REPORTED)'	Stella Yoon (b) (4)	24 Aug 2020 19:26:02
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:52:28**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:26:02
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:52:28**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'I'	Stella Yoon (b) (4)	24 Aug 2020 19:26:02
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:52:28**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:26:02
	(b) (4)	



**US3022291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:52:28**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:26:02
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:52:28**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:26:02
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:52:28**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:26:02
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:52:28**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:26:02
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:52:28**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:26:02
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:52:28**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:26:02
	(b) (4)	

US3022291

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:28

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '24 Aug 2020'	Chevon Roberts (b) (4)	24 Aug 2020 14:48:39
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:52:28**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Aug 2020'	(b) (4), (b) (6) System	24 Aug 2020 14:48:39



**US3022291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:52:28**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '2020'	(b) (4), (b) (6) System	24 Aug 2020 14:48:39

**US3022291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:52:28**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Amendment 2 (2)'	Chevon Roberts (b) (4)	24 Aug 2020 14:48:39
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:52:28**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Aug 2020 14:48:39
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:52:28**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Aug 2020 14:48:39
	(b) (4)	

US3022291

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:28

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Aug 2020 14:48:39
	(b) (4)	

US3022291

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:28

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	Chevon Roberts (b) (4)	24 Aug 2020 14:48:39
	(b) (4)	

US3022291

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:52:28

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	RWS_ENDPOINT	24 Aug 2020 12:19:28
	ENDPOINT (b) (4)	
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:52:28**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'I'	(b) (4), (b) (6) System	24 Aug 2020 14:48:42



US3022291

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	24 Aug 2020 14:48:42
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 14:52:28**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:26:24
	(b) (4)	

US3022291

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:52:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 21:46:16
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' answered with 'NO MEDS TAKEN FOR THIS ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:42:09
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 08:24:41
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:27:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:27:43
Data point term sent to Coder	System	24 Aug 2020 19:26:39
User entered 'Asthma'	Stella Yoon (b) (4)	24 Aug 2020 19:26:37

**US3022291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'un UNK 1980'	Stella Yoon (b) (4)	24 Aug 2020 19:26:37

**US3022291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:26:37

**US3022291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:26:37

**US3022291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:52:28**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:26:37

**US3022291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:26:37



**US3022291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Jan 1980'	System	24 Aug 2020 19:26:37

**US3022291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '1980'	System	24 Aug 2020 19:26:37

**US3022291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered empty.	System	24 Aug 2020 19:26:37

**US3022291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered empty.	System	24 Aug 2020 19:26:37

US3022291

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 13:36:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 13:36:45
Data point term sent to Coder	System	04 Feb 2021 13:36:07
Coding entries removed.	(b) (4), (b) (6)	04 Feb 2021 13:35:37
User entered 'RIGHT KNEE OSTEOARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Feb 2021 13:35:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:29:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:29:38
Data point term sent to Coder	System	24 Aug 2020 19:28:46
User entered 'right knee arthritis'	Stella Yoon (b) (4)	24 Aug 2020 19:28:39

**US3022291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'un UNK 2019'	Stella Yoon (b) (4)	24 Aug 2020 19:28:39

US3022291

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:52:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:28:39

**US3022291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:28:39



**US3022291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:52:28**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:28:39

**US3022291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:28:39

**US3022291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Jan 2019'	System	24 Aug 2020 19:28:39

**US3022291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '2019'	System	24 Aug 2020 19:28:39

**US3022291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered empty.	System	24 Aug 2020 19:28:39

**US3022291**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered empty.	System	24 Aug 2020 19:28:39

US3022291

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:52:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:30:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:30:35
Data point term sent to Coder	System	24 Aug 2020 19:29:47
User entered 'Hypertension'	Stella Yoon (b) (4)	24 Aug 2020 19:28:54

**US3022291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'un UNK 2005'	Stella Yoon (b) (4)	24 Aug 2020 19:28:54



**US3022291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:28:54

**US3022291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:28:54

**US3022291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:52:28**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:28:54

**US3022291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:28:54

**US3022291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Jan 2005'	System	24 Aug 2020 19:28:54

**US3022291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '2005'	System	24 Aug 2020 19:28:54

**US3022291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered empty.	System	24 Aug 2020 19:28:54

**US3022291**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered empty.	System	24 Aug 2020 19:28:54



US3022291

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:30:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:30:37
Data point term sent to Coder	System	24 Aug 2020 19:29:48
User entered 'tubal ligation'	Stella Yoon (b) (4)	24 Aug 2020 19:29:13

US3022291

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:52:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'un UNK 2006'	Stella Yoon (b) (4)	24 Aug 2020 19:29:13

**US3022291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:29:13

**US3022291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:29:13

**US3022291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:52:28**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'un UNK 2006'	Stella Yoon (b) (4)	24 Aug 2020 19:29:13

**US3022291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:29:13

**US3022291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Jan 2006'	System	24 Aug 2020 19:29:13

**US3022291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '2006'	System	24 Aug 2020 19:29:13



**US3022291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Jan 2006'	System	24 Aug 2020 19:29:13

**US3022291**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '2006'	System	24 Aug 2020 19:29:13

US3022291

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User closed query 'Per CDM: Thank you for confirming procedure was for weight loss. Please consider adding associated condition of obesity on Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 13:06:36
Query 'Per CDM: Thank you for confirming procedure was for weight loss. Please consider adding associated condition of obesity on Med History eCRF.' answered with 'updated' (Site from DM).	Stella Yoon (b) (4)	01 Oct 2020 19:07:52
User opened query 'Per CDM: Thank you for confirming procedure was for weight loss. Please consider adding associated condition of obesity on Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:22:24
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 14:22:24
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' answered with 'NO OTHER CONDITON LED TO THIS. DID THIS FOR WEIGHT LOSS' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:44:08
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 08:25:24

US3022291

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:52:28

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:30:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:30:37
Data point term sent to Coder	System	24 Aug 2020 19:29:48
User entered 'Gastric Bypass'	Stella Yoon (b) (4)	24 Aug 2020 19:29:32
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'un UNK 2008'	Stella Yoon (b) (4)	24 Aug 2020 19:29:32

**US3022291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:29:32

**US3022291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:29:32

**US3022291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:52:28**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'un UNK 2008'	Stella Yoon (b) (4)	24 Aug 2020 19:29:32



**US3022291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:29:32

**US3022291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Jan 2008'	System	24 Aug 2020 19:29:32

**US3022291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '2008'	System	24 Aug 2020 19:29:32

**US3022291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Jan 2008'	System	24 Aug 2020 19:29:32

**US3022291**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '2008'	System	24 Aug 2020 19:29:32

US3022291

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:52:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric ulcer surgery, LLT: Gastric ulcer surgery - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:09:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 21:09:41
Data point term sent to Coder	System	17 Sep 2020 21:08:03
User closed query 'DM-Coding: Please clarify the type/location of ulcer. Please update the reported term.' (Site from System).	System	17 Sep 2020 21:07:17
Query 'DM-Coding: Please clarify the type/location of ulcer. Please update the reported term.' answered with 'updated' (Site from System).	Stella Yoon (b) (4)	17 Sep 2020 21:07:17
User entered 'stomach ULCER SURGERY' reason for change: Data Entry Error	Stella Yoon (b) (4)	17 Sep 2020 21:07:12
User opened query 'DM-Coding: Please clarify the type/location of ulcer. Please update the reported term.' (Site from System).	Coder Import (b) (4)	09 Sep 2020 06:26:33
Data point term sent to Coder	System	24 Aug 2020 19:29:50
User entered 'Ulcer surgery'	Stella Yoon (b) (4)	24 Aug 2020 19:29:47

**US3022291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'un UNK 2016'	Stella Yoon (b) (4)	24 Aug 2020 19:29:47

**US3022291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:29:47



**US3022291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:29:47

**US3022291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:52:28**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'un UNK 2016'	Stella Yoon (b) (4)	24 Aug 2020 19:29:47

**US3022291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:29:47

**US3022291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Jan 2016'	System	24 Aug 2020 19:29:47

**US3022291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '2016'	System	24 Aug 2020 19:29:47

**US3022291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Jan 2016'	System	24 Aug 2020 19:29:47

**US3022291**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '2016'	System	24 Aug 2020 19:29:47

US3022291

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:52:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric ulcer, LLT: Stomach ulcer - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:31:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 19:31:40
Data point term sent to Coder	System	24 Aug 2020 19:30:51
User entered 'Stomach Ulcer'	Stella Yoon (b) (4)	24 Aug 2020 19:30:05



**US3022291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'un UNK 2016'	Stella Yoon (b) (4)	24 Aug 2020 19:30:05

**US3022291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:30:05

**US3022291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:30:05

**US3022291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:52:28**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'un UNK 2016'	Stella Yoon (b) (4)	24 Aug 2020 19:30:05

**US3022291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:30:05

**US3022291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Jan 2016'	System	24 Aug 2020 19:30:05

**US3022291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '2016'	System	24 Aug 2020 19:30:05

**US3022291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Jan 2016'	System	24 Aug 2020 19:30:05



**US3022291**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '2016'	System	24 Aug 2020 19:30:05

US3022291

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:52:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 19:09:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 19:09:21
Data point term sent to Coder	System	01 Oct 2020 19:07:43
User entered 'obesity'	Stella Yoon (b) (4)	01 Oct 2020 19:07:41

**US3022291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'un (b) (6) 1975'	Stella Yoon (b) (4)	01 Oct 2020 19:07:41

**US3022291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	01 Oct 2020 19:07:41

**US3022291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:52:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	Stella Yoon (b) (4)	01 Oct 2020 19:07:41

**US3022291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:52:28**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered empty.	Stella Yoon (b) (4)	01 Oct 2020 19:07:41

**US3022291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	Stella Yoon (b) (4)	01 Oct 2020 19:07:41

US3022291

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:52:28

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered (b) (6) 1975'	System	01 Oct 2020 19:07:41



**US3022291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '1975'	System	01 Oct 2020 19:07:41

**US3022291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered empty.	System	01 Oct 2020 19:07:41

**US3022291**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered empty.	System	01 Oct 2020 19:07:41

US3022291

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:52:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 18:35:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 18:35:01
Data point term sent to Coder	System	22 Feb 2021 18:34:33
User entered 'INSOMNIA'	(b) (4), (b) (6)	22 Feb 2021 18:33:32

**US3022291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'UN UNK 2014'	(b) (4), (b) (6)	22 Feb 2021 18:33:32

**US3022291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 18:33:32

**US3022291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:52:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:33:32

**US3022291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:52:28**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 18:33:32



**US3022291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	(b) (4), (b) (6)	22 Feb 2021 18:33:32

**US3022291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Jan 2014'	System	22 Feb 2021 18:33:32

**US3022291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '2014'	System	22 Feb 2021 18:33:32

**US3022291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered empty.	System	22 Feb 2021 18:33:32

**US3022291**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered empty.	System	22 Feb 2021 18:33:32

US3022291

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:52:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User coded data point as SOC: Psychiatric disorders, HLT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 14:19:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 14:19:55
Data point term sent to Coder	System	22 Apr 2021 14:19:38
User entered 'depression'	(b) (4), (b) (6)	22 Apr 2021 14:19:28

**US3022291**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'un UNK 2015'	(b) (4), (b) (6)	22 Apr 2021 14:19:28

**US3022291**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 14:19:28



**US3022291**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:52:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 14:19:28

**US3022291**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:52:28**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 14:19:28

**US3022291**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 14:19:28

**US3022291**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered 'Jan 2015'	System	22 Apr 2021 14:19:28

**US3022291**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:52:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered '2015'	System	22 Apr 2021 14:19:28

**US3022291**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered empty.	System	22 Apr 2021 14:19:28

**US3022291**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 14:52:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:58:42
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 07:38:15
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
User entered empty.	System	22 Apr 2021 14:19:28

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:31:27
	(b) (4)	



**US3022291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '24 Aug 2020'	Stella Yoon (b) (4)	24 Aug 2020 19:31:27
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '08:09'	Stella Yoon (b) (4)	24 Aug 2020 19:31:27
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
User entered '24 Aug 2020 08:09'	(b) (4), (b) (6) System	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '171' cm	Stella Yoon (b) (4)	24 Aug 2020 19:31:27
	(b) (4)	
DataPoint set to visible.	System	24 Aug 2020 14:48:42

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '118.2' kg	Stella Yoon (b) (4)	24 Aug 2020 19:31:27
	(b) (4)	
DataPoint set to visible.	System	24 Aug 2020 14:48:42

**US3022291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
Amendment Manager: User entered '40.42269'	(b) (4), (b) (6)	
User entered '40.4'	System	17 Sep 2020 00:20:43
DataPoint set to visible.	System	24 Aug 2020 19:31:27
	System	24 Aug 2020 14:48:42

**US3022291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	24 Aug 2020 19:31:27
DataPoint set to visible.	System	24 Aug 2020 14:48:42

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 06:02:29
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 14:59:33
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 14:59:20
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)	22 Oct 2020 13:04:06
User entered '36.5' C	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:31:27



US3022291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:59:20
	(b) (4)	
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	24 Aug 2020 19:31:27
	(b) (4)	

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:31:27
	(b) (4)	

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:59:20
	(b) (4)	
User entered '76'	Stella Yoon (b) (4)	24 Aug 2020 19:31:27
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
User entered 'bpm'	(b) (4), (b) (6) System	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:59:20
	(b) (4)	
User entered '13'	Stella Yoon (b) (4)	24 Aug 2020 19:31:27
	(b) (4)	

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:59:20
	(b) (4)	
User entered '122'	Stella Yoon (b) (4)	24 Aug 2020 19:31:27
	(b) (4)	

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 19:31:27



US3022291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:59:20
	(b) (4)	
User entered '84'	Stella Yoon (b) (4)	24 Aug 2020 19:31:27
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 19:31:27

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:42:53

US3022291

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:42:53

US3022291

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:31:36
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:52:28**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '24 Aug 2020'	Stella Yoon (b) (4)	24 Aug 2020 19:31:36
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:52:28**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '24 Aug 2020'	Stella Yoon (b) (4)	24 Aug 2020 19:31:43
	(b) (4)	

US3022291

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:28

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:31:43
	(b) (4)	



US3022291

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:28

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:31:43
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:52:28**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:31:43
	(b) (4)	

US3022291

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:28

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:31:43
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:52:28**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:31:43
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 14:52:28**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:31:43
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:52:28

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:31:43
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:31
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '24 Aug 2020'	Stella Yoon (b) (4)	24 Aug 2020 19:32:31
	(b) (4)	



**US3022291**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Serum (SERUM)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:31
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:31
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:31
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:32:31
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:32:31
	(b) (4)	

**US3022291**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 19:32:31

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	



US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	



US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:10

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'I'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	



US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Stella Yoon (b) (4)	24 Aug 2020 19:32:21
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

US3022291

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:52:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:42:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User closed query 'Other specified is provided for Location and Living Circumstances Risk, but OTHER is not selected for Location and Living Circumstances Risk. Please reconcile.' (Site from System).	System	24 Aug 2020 19:32:21
User opened query 'Other specified is provided for Location and Living Circumstances Risk, but OTHER is not selected for Location and Living Circumstances Risk. Please reconcile.' (Site from System).	System	24 Aug 2020 19:32:10
User entered 'lives in community with ongoing person to person transmission'	Stella Yoon (b) (4)	24 Aug 2020 19:32:10
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:40
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '24 Aug 2020'	Stella Yoon (b) (4)	24 Aug 2020 19:32:40
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Clinic (Clinic)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:40
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'VISIT1'	(b) (4), (b) (6) System	24 Aug 2020 19:32:40

US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '24 AUG 2020'	RWS_ENDPOINT	24 Aug 2020 13:19:58
	ENDPOINT (b) (4)	
	(b) (4)	



US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:28

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '144809'	RWS_ENDPOINT	24 Aug 2020 13:19:58
	ENDPOINT (b) (4)	
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:28

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	24 Aug 2020 13:19:58

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:52:28**

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:57

US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:28

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:32:57

US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:28

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:57
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:52:28**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:57
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:52:28**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	24 Aug 2020 19:32:57
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:52:28

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 12:44:36
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 18:39:50
	(b) (4)	
User entered 'No (N)'	Morgan Deal (b) (4)	12 Nov 2020 18:39:44
	(b) (4)	
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 19:02:31
	(b) (4), (b) (6)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:24:28



US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
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)	13 Nov 2020 06:53:49
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)	12 Nov 2020 14:57:32
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:57:04
	(b) (4)	
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)	23 Oct 2020 11:39:16
User entered '171' cm	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:57:04
	(b) (4)	
User entered '118.2' kg	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 06:53:49
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 14:57:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 14:57:04
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)	23 Oct 2020 11:39:16
User entered '171' cm	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered missing code ND - Not Done; reason for	Morgan Deal (b) (4)	12 Nov 2020 14:57:04
change Per Query Resolution	(b) (4)	
User entered '118.2' kg	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '24 Aug 2020'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '08:09'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05



**US3022291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered '24 Aug 2020 08:09'	(b) (4), (b) (6) System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '36.5' C	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '76'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'bpm'	(b) (4), (b) (6) System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '13'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Aug 2020 19:34:05



US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '122'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '84'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 06:53:49
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 14:57:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 14:57:04
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)	23 Oct 2020 11:39:16
User entered '171' cm	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered missing code ND - Not Done; reason for	Morgan Deal (b) (4)	12 Nov 2020 14:57:04
change Per Query Resolution	(b) (4)	
User entered '118.2' kg	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	



US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '24 Aug 2020'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '10:50'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered '24 Aug 2020 10:50'	(b) (4), (b) (6) System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '36.5' C	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '66'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'bpm'	(b) (4), (b) (6) System	24 Aug 2020 19:34:05



US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '14'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'breaths/min'	(b) (4), (b) (6) System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '124'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '82'	Stella Yoon (b) (4)	24 Aug 2020 19:34:05
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'mmHg'	(b) (4), (b) (6) System	24 Aug 2020 19:34:05

US3022291

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:34:11
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '24 Aug 2020'	Stella Yoon (b) (4)	24 Aug 2020 19:34:11
	(b) (4)	



US3022291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:52:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User closed query 'Per CDM: Screening and V1D1 have occurred on the same day and data reported on this page is to be recorded on Pregnancy test form at Screening. Please consider to mark responses for "Was the pregnancy test performed?" as No and make the rest of the data points on this page blank. Refer to page 24 of CCGs for more details. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:01:30
Query 'Per CDM: Screening and V1D1 have occurred on the same day and data reported on this page is to be recorded on Pregnancy test form at Screening. Please consider to mark responses for "Was the pregnancy test performed?" as No and make the rest of the data points on this page blank. Refer to page 24 of CCGs for more details. Thank you.' answered with 'fixed' (Site from DM).	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:06:39
User entered 'No (N)' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:06:28
User opened query 'Per CDM: Screening and V1D1 have occurred on the same day and data reported on this page is to be recorded on Pregnancy test form at Screening. Please consider to mark responses for "Was the pregnancy test performed?" as No and make the rest of the data points on this page blank. Refer to page 24 of CCGs for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 11:05:32
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:19

US3022291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:52:28

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty; reason for change Data Entry Error	Stella Yoon (b) (4)	17 Sep 2020 21:06:28
	(b) (4)	
User entered '24 Aug 2020'	Stella Yoon (b) (4)	24 Aug 2020 19:34:19
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:52:28

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty; reason for change Data Entry Error	Stella Yoon (b) (4)	17 Sep 2020 21:06:28
	(b) (4)	
User entered 'Urine (URINE)'	Stella Yoon (b) (4)	24 Aug 2020 19:34:19
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:52:28

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty; reason for change Data Entry Error	Stella Yoon (b) (4)	17 Sep 2020 21:06:28
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Stella Yoon (b) (4)	24 Aug 2020 19:34:19
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:52:28

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User closed query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 10:46:52
Query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 19:29:09
User entered 'No (N)' reason for change: Data Entry Error	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 19:29:03
User opened query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 08:44:51
User entered empty.	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:19

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:34:19
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:34:19
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 19:34:19



US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Aug 2020 14:49:01
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered empty.	(b) (4) Chevon Roberts (b) (4)	24 Aug 2020 14:49:01
	(b) (4)	

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '24 Aug 2020'	(b) (4) Chevon Roberts (b) (4)	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '10:17'	(b) (4) Chevon Roberts (b) (4)	24 Aug 2020 14:49:01

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered '24 Aug 2020 10:17'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Left Arm (LEFT ARM)'	(b) (4) Chevon Roberts (b) (4)	24 Aug 2020 14:49:01



US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'ONCE'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:34:37
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '24 Aug 2020'	Stella Yoon (b) (4)	24 Aug 2020 19:34:37
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '09:12'	Stella Yoon (b) (4)	24 Aug 2020 19:34:37
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered '24 Aug 2020 09:12'	(b) (4), (b) (6) System	24 Aug 2020 19:34:37

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 14:52:28**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '24 Aug 2020'	Stella Yoon (b) (4)	24 Aug 2020 19:34:52
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:52



**US3022291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:52

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:52:28**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '08:50'	Stella Yoon (b) (4)	24 Aug 2020 19:34:52
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered '24 Aug 2020 08:50'	(b) (4), (b) (6) System	24 Aug 2020 19:34:52

US3022291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:52:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:52

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:34:52

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	24 Aug 2020 19:34:52
	(b) (4)	

**US3022291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered empty.	(b) (4), (b) (6) System	24 Aug 2020 19:34:52

US3022291

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:52:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	24 Aug 2020 19:34:58
	(b) (4)	



**US3022291**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'I'	(b) (4), (b) (6) System	24 Aug 2020 19:34:58

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
	(b) (4), (b) (6)	
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:50:52', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '29cc00c7-66c6-4c02-9b48-1d01aecc11f8' User entered 'Yes (Y)'	System	24 Aug 2020 14:51:07
	System	24 Aug 2020 14:51:07

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:50:56', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '29cc00c7-66c6-4c02-9b48-1d01aecc11f8' User entered '97.6'	System	24 Aug 2020 14:51:07
	System	24 Aug 2020 14:51:07

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:51:01', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '29cc00c7-66c6-4c02-9b48-1d01aecc11f8'	(b) (4), (b) (6)	
System		24 Aug 2020 14:51:07
User entered 'No (N)'	System	24 Aug 2020 14:51:07

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:51:05', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '29cc00c7-66c6-4c02-9b48-1d01aecc11f8' User entered '24 Aug 2020 10:51'	System	24 Aug 2020 14:51:07
	System	24 Aug 2020 14:51:07

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '24 Aug 2020 10:37'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '24 Aug 2020 13:07'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01



US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
	(b) (4), (b) (6)	
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:21:53', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '77a690f0-7d6a-4490-b852-2d784790e98a' User entered 'Yes (Y)'	System	25 Aug 2020 13:22:04
	System	25 Aug 2020 13:22:04

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:21:56', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '77a690f0-7d6a-4490-b852-2d784790e98a' User entered '96.1'	System	25 Aug 2020 13:22:04
	System	25 Aug 2020 13:22:04

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '77a690f0-7d6a-4490-b852-2d784790e98a' User entered 'No (N)'	System	25 Aug 2020 13:22:04
	System	25 Aug 2020 13:22:04

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:03', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '77a690f0-7d6a-4490-b852-2d784790e98a' User entered '25 Aug 2020 09:22'	System	25 Aug 2020 13:22:04
	System	25 Aug 2020 13:22:04

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '24 Aug 2020 14:02'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 2'	System	24 Aug 2020 14:49:01



US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:09', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7e5d8d8f-7ad8-43df-919d-7938ce35fd4a' User entered 'Yes (Y)'	System	26 Aug 2020 09:29:25
	System	26 Aug 2020 09:29:25

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:14', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7e5d8d8f-7ad8-43df-919d-7938ce35fd4a' User entered '97.2'	System	26 Aug 2020 09:29:25
	System	26 Aug 2020 09:29:25

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:18', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7e5d8d8f-7ad8-43df-919d-7938ce35fd4a'	(b) (4), (b) (6)	
	System	26 Aug 2020 09:29:25
User entered 'No (N)'	System	26 Aug 2020 09:29:25

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:24', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7e5d8d8f-7ad8-43df-919d-7938ce35fd4a' User entered '26 Aug 2020 05:29'	System	26 Aug 2020 09:29:25
	System	26 Aug 2020 09:29:25

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:52:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 3'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'a41e7d1e-f1da-4e8e-85d2-bbadb875f7fc' User entered 'Yes (Y)'	System	27 Aug 2020 04:25:48
	System	27 Aug 2020 04:25:48



US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:40', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'a41e7d1e-f1da-4e8e-85d2-bbadb875f7fc' User entered '97.2'	System	27 Aug 2020 04:25:48
	System	27 Aug 2020 04:25:48

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:43', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'a41e7d1e-f1da-4e8e-85d2-bbadb875f7fc' User entered 'No (N)'	System	27 Aug 2020 04:25:48
	System	27 Aug 2020 04:25:48

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'a41e7d1e-f1da-4e8e-85d2-bbadb875f7fc' User entered '27 Aug 2020 00:25'	System	27 Aug 2020 04:25:48
	System	27 Aug 2020 04:25:48

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 4'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:02:58', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3aa00341-065e-4781-b1f0-7f9157be7484'	(b) (4), (b) (6)	
	System	28 Aug 2020 00:04:05
User entered 'Yes (Y)'	System	28 Aug 2020 00:04:05

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:03:57', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3aa00341-065e-4781-b1f0-7f9157be7484' User entered '96.4'	System	28 Aug 2020 00:04:05
	System	28 Aug 2020 00:04:05



US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3aa00341-065e-4781-b1f0-7f9157be7484'	(b) (4), (b) (6)	
	System	28 Aug 2020 00:04:05
User entered 'No (N)'	System	28 Aug 2020 00:04:05

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:03', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3aa00341-065e-4781-b1f0-7f9157be7484'	System	28 Aug 2020 00:04:05
User entered '27 Aug 2020 20:04'	System	28 Aug 2020 00:04:05

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 5'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:20', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '97bd78a0-3206-4313-aa60-df5ad8b263fd' User entered 'Yes (Y)'	System	29 Aug 2020 11:55:35
	System	29 Aug 2020 11:55:35

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:24', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '97bd78a0-3206-4313-aa60-df5ad8b263fd' User entered '97.3'	System	29 Aug 2020 11:55:35
	System	29 Aug 2020 11:55:35

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:27', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '97bd78a0-3206-4313-aa60-df5ad8b263fd' User entered 'No (N)'	System	29 Aug 2020 11:55:35
	System	29 Aug 2020 11:55:35



US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:52:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '97bd78a0-3206-4313-aa60-df5ad8b263fd' User entered '29 Aug 2020 07:55'	System	29 Aug 2020 11:55:35
	System	29 Aug 2020 11:55:35

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '29 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 6'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:23', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '73532dae-2e7c-44f1-88e6-2a404523158b' User entered 'Yes (Y)'	System	30 Aug 2020 12:26:40
	System	30 Aug 2020 12:26:40

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:33', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '73532dae-2e7c-44f1-88e6-2a404523158b' User entered '97.0'	(b) (4), (b) (6) System	30 Aug 2020 12:26:40
	System	30 Aug 2020 12:26:40

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:36', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '73532dae-2e7c-44f1-88e6-2a404523158b' User entered 'No (N)'	System	30 Aug 2020 12:26:40
	System	30 Aug 2020 12:26:40

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:38', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '73532dae-2e7c-44f1-88e6-2a404523158b' User entered '30 Aug 2020 08:26'	System	30 Aug 2020 12:26:40
	System	30 Aug 2020 12:26:40



US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:52:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '29 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:52:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '30 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 7'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:21:59', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '44877878-ef25-463d-8554-7eea0ba3bfd4'	(b) (4), (b) (6)	
	System	31 Aug 2020 02:22:17
User entered 'Yes (Y)'	System	31 Aug 2020 02:22:17

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:02', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '44877878-ef25-463d-8554-7eea0ba3bfd4' User entered '94.3'	(b) (4), (b) (6) System	31 Aug 2020 02:22:17
	System	31 Aug 2020 02:22:17

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:05', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '44877878-ef25-463d-8554-7eea0ba3bfd4'	(b) (4), (b) (6)	
	System	31 Aug 2020 02:22:17
User entered 'No (N)'	System	31 Aug 2020 02:22:17

US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:52:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:15', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '44877878-ef25-463d-8554-7eea0ba3bfd4'	(b) (4), (b) (6)	
	System	31 Aug 2020 02:22:17
User entered '30 Aug 2020 22:22'	System	31 Aug 2020 02:22:17

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '30 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01



US3022291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:52:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '31 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
	(b) (4), (b) (6)	
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:51:59', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '19887c33-c3ea-4fe4-af1f-1a316ee5a29c'	(b) (4), (b) (6)	
	System	24 Aug 2020 14:52:26
User entered 'None (1)'	System	24 Aug 2020 14:52:26

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:13', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '19887c33-c3ea-4fe4-af1f-1a316ee5a29c' User entered 'No (N)'	System	24 Aug 2020 14:52:26
	System	24 Aug 2020 14:52:26

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:16', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '19887c33-c3ea-4fe4-af1f-1a316ee5a29c' User entered 'No (N)'	System	24 Aug 2020 14:52:26
	System	24 Aug 2020 14:52:26

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:18', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '19887c33-c3ea-4fe4-af1f-1a316ee5a29c'	(b) (4), (b) (6)	24 Aug 2020 14:52:26
User entered 'None (1)'	System	24 Aug 2020 14:52:26

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:21', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '19887c33-c3ea-4fe4-af1f-1a316ee5a29c'	(b) (4), (b) (6)	
	System	24 Aug 2020 14:52:26
User entered '24 Aug 2020 10:52'	System	24 Aug 2020 14:52:26

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '24 Aug 2020 10:37'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01



**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '24 Aug 2020 13:07'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
	(b) (4), (b) (6)	
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:08', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '86545e39-6414-4021-a35e-910de966b38e' User entered 'None (1)'	System	25 Aug 2020 13:22:27
	System	25 Aug 2020 13:22:27

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:14', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '86545e39-6414-4021-a35e-910de966b38e' User entered 'No (N)'	System	25 Aug 2020 13:22:27
	System	25 Aug 2020 13:22:27

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:16', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '86545e39-6414-4021-a35e-910de966b38e' User entered 'No (N)'	System	25 Aug 2020 13:22:27
	System	25 Aug 2020 13:22:27

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:22', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '86545e39-6414-4021-a35e-910de966b38e' User entered 'None (1)'	System	25 Aug 2020 13:22:27
	System	25 Aug 2020 13:22:27

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:25', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '86545e39-6414-4021-a35e-910de966b38e' User entered '25 Aug 2020 09:22'	System	25 Aug 2020 13:22:27
	System	25 Aug 2020 13:22:27

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '24 Aug 2020 14:02'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01



**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
	(b) (4), (b) (6)	
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 2'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:34', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e1b4546e-40b8-4df9-9cec-f023e64b591b' User entered 'None (1)'	System	26 Aug 2020 09:29:46
	System	26 Aug 2020 09:29:46

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e1b4546e-40b8-4df9-9cec-f023e64b591b' User entered 'No (N)'	System	26 Aug 2020 09:29:46
	System	26 Aug 2020 09:29:46

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:40', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e1b4546e-40b8-4df9-9cec-f023e64b591b' User entered 'No (N)'	System	26 Aug 2020 09:29:46
	System	26 Aug 2020 09:29:46

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:43', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e1b4546e-40b8-4df9-9cec-f023e64b591b' User entered 'None (1)'	System	26 Aug 2020 09:29:46
	System	26 Aug 2020 09:29:46

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e1b4546e-40b8-4df9-9cec-f023e64b591b' User entered '26 Aug 2020 05:29'	System	26 Aug 2020 09:29:46
	System	26 Aug 2020 09:29:46

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01



**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
	(b) (4), (b) (6)	
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 3'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:50', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc21f545-edb4-4a42-9864-18d1b8bc57d9'	(b) (4), (b) (6) System	27 Aug 2020 04:26:02
User entered 'None (1)'	System	27 Aug 2020 04:26:02

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:52:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:52', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc21f545-edb4-4a42-9864-18d1b8bc57d9'	(b) (4), (b) (6)	
	System	27 Aug 2020 04:26:02
User entered 'No (N)'	System	27 Aug 2020 04:26:02

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc21f545-edb4-4a42-9864-18d1b8bc57d9'	System	27 Aug 2020 04:26:02
User entered 'No (N)'	System	27 Aug 2020 04:26:02

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:25:57', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc21f545-edb4-4a42-9864-18d1b8bc57d9'	(b) (4), (b) (6) System	27 Aug 2020 04:26:02
User entered 'None (1)'	System	27 Aug 2020 04:26:02

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc21f545-edb4-4a42-9864-18d1b8bc57d9'	(b) (4), (b) (6) System	27 Aug 2020 04:26:02
User entered '27 Aug 2020 00:26'	System	27 Aug 2020 04:26:02

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01



**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 4'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:14', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'b4b2b663-2fec-4825-ab37-947fe9edc4ce'	(b) (4), (b) (6) System	28 Aug 2020 00:04:31
User entered 'None (1)'	System	28 Aug 2020 00:04:31

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:17', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'b4b2b663-2fec-4825-ab37-947fe9edc4ce'	(b) (4), (b) (6)	28 Aug 2020 00:04:31
User entered 'No (N)'	System	28 Aug 2020 00:04:31

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:20', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'b4b2b663-2fec-4825-ab37-947fe9edc4ce'	System	28 Aug 2020 00:04:31
User entered 'No (N)'	System	28 Aug 2020 00:04:31

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:24', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'b4b2b663-2fec-4825-ab37-947fe9edc4ce'	System	28 Aug 2020 00:04:31
User entered 'None (1)'	System	28 Aug 2020 00:04:31

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:27', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'b4b2b663-2fec-4825-ab37-947fe9edc4ce' User entered '27 Aug 2020 20:04'	System	28 Aug 2020 00:04:31
	System	28 Aug 2020 00:04:31

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01



**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 5'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:05', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cc08220-39cc-4aaf-be3d-806c0daf77d5'	(b) (4), (b) (6) System	29 Aug 2020 11:55:18
User entered 'None (1)'	System	29 Aug 2020 11:55:18

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:52:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:08', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cc08220-39cc-4aaf-be3d-806c0daf77d5'	(b) (4), (b) (6)	
	System	29 Aug 2020 11:55:18
User entered 'No (N)'	System	29 Aug 2020 11:55:18

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:10', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cc08220-39cc-4aaf-be3d-806c0daf77d5'	System	29 Aug 2020 11:55:18
User entered 'No (N)'	System	29 Aug 2020 11:55:18

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:13', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cc08220-39cc-4aaf-be3d-806c0daf77d5'	(b) (4), (b) (6)	
	System	29 Aug 2020 11:55:18
User entered 'None (1)'	System	29 Aug 2020 11:55:18

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:15', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cc08220-39cc-4aaf-be3d-806c0daf77d5'	System	29 Aug 2020 11:55:18
User entered '29 Aug 2020 07:55'	System	29 Aug 2020 11:55:18

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01



**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '29 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
	(b) (4), (b) (6)	
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 6'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:42', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '1844fa4d-f8ac-4f4d-b103-3140743dd065'	(b) (4), (b) (6)	
	System	30 Aug 2020 12:26:54
User entered 'None (1)'	System	30 Aug 2020 12:26:54

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '1844fa4d-f8ac-4f4d-b103-3140743dd065' User entered 'No (N)'	System	30 Aug 2020 12:26:54
	System	30 Aug 2020 12:26:54

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:48', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '1844fa4d-f8ac-4f4d-b103-3140743dd065'	(b) (4), (b) (6)	
	System	30 Aug 2020 12:26:54
User entered 'No (N)'	System	30 Aug 2020 12:26:54

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:50', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '1844fa4d-f8ac-4f4d-b103-3140743dd065'	System	30 Aug 2020 12:26:54
User entered 'None (1)'	System	30 Aug 2020 12:26:54

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:52', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '1844fa4d-f8ac-4f4d-b103-3140743dd065' User entered '30 Aug 2020 08:26'	System	30 Aug 2020 12:26:54
	System	30 Aug 2020 12:26:54

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '29 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01



**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '30 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 7'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:19', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ffb7b272-b42e-4418-86d5-2cc32afeeda3'	(b) (4), (b) (6) System	31 Aug 2020 02:22:33
User entered 'None (1)'	System	31 Aug 2020 02:22:33

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:23', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ffb7b272-b42e-4418-86d5-2cc32afeeda3' User entered 'No (N)'	System	31 Aug 2020 02:22:33
	System	31 Aug 2020 02:22:33

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:26', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ffb7b272-b42e-4418-86d5-2cc32afeeda3' User entered 'No (N)'	System	31 Aug 2020 02:22:33
	System	31 Aug 2020 02:22:33

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:28', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ffb7b272-b42e-4418-86d5-2cc32afeeda3'	(b) (4), (b) (6) System	31 Aug 2020 02:22:33
User entered 'None (1)'	System	31 Aug 2020 02:22:33

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:30', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ffb7b272-b42e-4418-86d5-2cc32afeeda3' User entered '30 Aug 2020 22:22'	(b) (4), (b) (6) System	31 Aug 2020 02:22:33
	System	31 Aug 2020 02:22:33

US3022291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '30 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01



**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '31 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
	(b) (4), (b) (6)	
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:26', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18' User entered 'None (0)'	System	24 Aug 2020 14:52:47
	System	24 Aug 2020 14:52:47

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18' User entered 'None (0)'	System	24 Aug 2020 14:52:47
	System	24 Aug 2020 14:52:47

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:32', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18' User entered 'None (0)'	System	24 Aug 2020 14:52:47
	System	24 Aug 2020 14:52:47

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:34', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18' User entered 'None (0)'	System	24 Aug 2020 14:52:47
	System	24 Aug 2020 14:52:47

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:36', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18' User entered 'None (0)'	System	24 Aug 2020 14:52:47
	System	24 Aug 2020 14:52:47

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:39', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18' User entered 'None (0)'	System	24 Aug 2020 14:52:47
	System	24 Aug 2020 14:52:47



US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:44', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18' User entered 'No (N)'	System	24 Aug 2020 14:52:47
	System	24 Aug 2020 14:52:47

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-24T10:52:46', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0fe09150-519e-404c-88b0-4e303b10ea18' User entered '24 Aug 2020 10:52'	System	24 Aug 2020 14:52:47
	System	24 Aug 2020 14:52:47

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '24 Aug 2020 10:37'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '24 Aug 2020 13:07'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
	(b) (4), (b) (6)	
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18' User entered 'None (0)'	System	25 Aug 2020 13:22:52
	System	25 Aug 2020 13:22:52

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:31', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18' User entered 'None (0)'	System	25 Aug 2020 13:22:52
	System	25 Aug 2020 13:22:52

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:33', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18' User entered 'None (0)'	System	25 Aug 2020 13:22:52
	System	25 Aug 2020 13:22:52



US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:35', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18' User entered 'None (0)'	System	25 Aug 2020 13:22:52
	System	25 Aug 2020 13:22:52

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18' User entered 'None (0)'	System	25 Aug 2020 13:22:52
	System	25 Aug 2020 13:22:52

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:39', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18' User entered 'None (0)'	System	25 Aug 2020 13:22:52
	System	25 Aug 2020 13:22:52

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18' User entered 'No (N)'	System	25 Aug 2020 13:22:52
	System	25 Aug 2020 13:22:52

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-25T09:22:47', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fb099950-be14-4d83-a099-a7543166eb18' User entered '25 Aug 2020 09:22'	System	25 Aug 2020 13:22:52
	System	25 Aug 2020 13:22:52

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '24 Aug 2020 14:02'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 2'	System	24 Aug 2020 14:49:01



US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:49', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78' User entered 'None (0)'	System	26 Aug 2020 09:30:06
	System	26 Aug 2020 09:30:06

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:51', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78' User entered 'None (0)'	System	26 Aug 2020 09:30:06
	System	26 Aug 2020 09:30:06

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:53', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78' User entered 'None (0)'	System	26 Aug 2020 09:30:06
	System	26 Aug 2020 09:30:06

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78' User entered 'None (0)'	System	26 Aug 2020 09:30:06
	System	26 Aug 2020 09:30:06

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:29:58', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78' User entered 'None (0)'	System	26 Aug 2020 09:30:06
	System	26 Aug 2020 09:30:06

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:30:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78' User entered 'None (0)'	System	26 Aug 2020 09:30:06
	System	26 Aug 2020 09:30:06

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:30:03', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78'	System	26 Aug 2020 09:30:06
User entered 'No (N)'	System	26 Aug 2020 09:30:06

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-26T05:30:05', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '35a90924-c4bd-46c4-82e8-7238d1dc2c78'	System	26 Aug 2020 09:30:06
User entered '26 Aug 2020 05:30'	System	26 Aug 2020 09:30:06



**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
	(b) (4), (b) (6)	
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 3'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:04', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1' User entered 'None (0)'	System	27 Aug 2020 04:26:23
	System	27 Aug 2020 04:26:23

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:07', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1' User entered 'None (0)'	System	27 Aug 2020 04:26:23
	System	27 Aug 2020 04:26:23

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:09', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1' User entered 'None (0)'	System	27 Aug 2020 04:26:23
	System	27 Aug 2020 04:26:23

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:11', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1' User entered 'None (0)'	System	27 Aug 2020 04:26:23
	System	27 Aug 2020 04:26:23

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:13', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1' User entered 'None (0)'	System	27 Aug 2020 04:26:23
	System	27 Aug 2020 04:26:23



**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:15', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1' User entered 'None (0)'	System	27 Aug 2020 04:26:23
	System	27 Aug 2020 04:26:23

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:18', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1'	System	27 Aug 2020 04:26:23
User entered 'No (N)'	System	27 Aug 2020 04:26:23

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T00:26:20', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fff53010-6cec-467e-a650-2f3beb9d15c1'	System	27 Aug 2020 04:26:23
User entered '27 Aug 2020 00:26'	System	27 Aug 2020 04:26:23

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 4'	System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198' User entered 'None (0)'	System	28 Aug 2020 00:04:57
	System	28 Aug 2020 00:04:57

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:39', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198' User entered 'None (0)'	System	28 Aug 2020 00:04:57
	System	28 Aug 2020 00:04:57



US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:42', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198' User entered 'None (0)'	System	28 Aug 2020 00:04:57
	System	28 Aug 2020 00:04:57

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:44', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198' User entered 'None (0)'	System	28 Aug 2020 00:04:57
	System	28 Aug 2020 00:04:57

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198' User entered 'None (0)'	System	28 Aug 2020 00:04:57
	System	28 Aug 2020 00:04:57

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:47', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198' User entered 'None (0)'	System	28 Aug 2020 00:04:57
	System	28 Aug 2020 00:04:57

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:53', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198'	System	28 Aug 2020 00:04:57
User entered 'No (N)'	System	28 Aug 2020 00:04:57

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-27T20:04:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8c5421ae-bf60-4d61-920b-565629d02198'	System	28 Aug 2020 00:04:57
User entered '27 Aug 2020 20:04'	System	28 Aug 2020 00:04:57

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '27 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01



US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 5'	System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:32', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9' User entered 'None (0)'	System	29 Aug 2020 11:55:51
	System	29 Aug 2020 11:55:51

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:35', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9' User entered 'None (0)'	System	29 Aug 2020 11:55:51
	System	29 Aug 2020 11:55:51

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9' User entered 'None (0)'	System	29 Aug 2020 11:55:51
	System	29 Aug 2020 11:55:51

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:39', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9' User entered 'None (0)'	System	29 Aug 2020 11:55:51
	System	29 Aug 2020 11:55:51

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:41', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9' User entered 'None (0)'	System	29 Aug 2020 11:55:51
	System	29 Aug 2020 11:55:51

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:42', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9' User entered 'None (0)'	System	29 Aug 2020 11:55:51
	System	29 Aug 2020 11:55:51

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:46', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9'	System	29 Aug 2020 11:55:51
User entered 'No (N)'	System	29 Aug 2020 11:55:51



**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-29T07:55:48', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9dfb32ac-6ff0-4ebb-be84-7b1b8898d4e9' User entered '29 Aug 2020 07:55'	System	29 Aug 2020 11:55:51
	System	29 Aug 2020 11:55:51

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '29 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
	(b) (4), (b) (6)	
Data entry locked.	System	24 Aug 2020 14:49:01
User entered 'Day 6'	System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:26:58', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137'	(b) (4), (b) (6)	
	System	30 Aug 2020 12:28:09
User entered 'None (0)'	System	30 Aug 2020 12:28:09

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:27:02', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137' User entered 'None (0)'	System	30 Aug 2020 12:28:09
	System	30 Aug 2020 12:28:09

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:27:09', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137' User entered 'None (0)'	System	30 Aug 2020 12:28:09
	System	30 Aug 2020 12:28:09

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:27:14', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137' User entered 'None (0)'	System	30 Aug 2020 12:28:09
	System	30 Aug 2020 12:28:09



US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:27:48', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137' User entered 'None (0)'	System	30 Aug 2020 12:28:09
	System	30 Aug 2020 12:28:09

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:28:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137' User entered 'None (0)'	System	30 Aug 2020 12:28:09
	System	30 Aug 2020 12:28:09

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:28:02', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137'	(b) (4), (b) (6)	
	System	30 Aug 2020 12:28:09
User entered 'No (N)'	System	30 Aug 2020 12:28:09

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T08:28:05', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'bb69faf3-1012-4d04-ab5e-c7c50e82f137'	(b) (4), (b) (6)	
	System	30 Aug 2020 12:28:09
User entered '30 Aug 2020 08:28'	System	30 Aug 2020 12:28:09

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '29 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '30 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 7'	System	24 Aug 2020 14:49:01

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:34', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d' User entered 'None (0)'	System	31 Aug 2020 02:22:54
	System	31 Aug 2020 02:22:54



US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:36', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d' User entered 'None (0)'	System	31 Aug 2020 02:22:54
	System	31 Aug 2020 02:22:54

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:38', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d' User entered 'None (0)'	System	31 Aug 2020 02:22:54
	System	31 Aug 2020 02:22:54

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:40', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d' User entered 'None (0)'	System	31 Aug 2020 02:22:54
	System	31 Aug 2020 02:22:54

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:43', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d' User entered 'None (0)'	System	31 Aug 2020 02:22:54
	System	31 Aug 2020 02:22:54

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:52:28**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d' User entered 'None (0)'	System	31 Aug 2020 02:22:54
	System	31 Aug 2020 02:22:54

US3022291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:47', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d' User entered 'No (N)'	System	31 Aug 2020 02:22:54
	System	31 Aug 2020 02:22:54

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-08-30T22:22:50', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '47960bdf-95fa-4f86-8733-c28446f2c47d' User entered '30 Aug 2020 22:22'	(b) (4), (b) (6) System	31 Aug 2020 02:22:54
	System	31 Aug 2020 02:22:54

**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '30 Aug 2020 12:00'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01



**US3022291**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '31 Aug 2020 11:59'	(b) (4), (b) (6) System	24 Aug 2020 14:49:01

**US3022291**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:13

**US3022291**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '31 Aug 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:13

**US3022291**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Shanice Bennett (b) (4)	16 Sep 2020 19:29:13

US3022291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	16 Sep 2020 19:29:13
	(b) (4)	

**US3022291**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4)	16 Sep 2020 19:29:17

**US3022291**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'I'	(b) (4), (b) (6) System	16 Sep 2020 19:29:17

**US3022291**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4)	16 Sep 2020 19:29:29



**US3022291**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '07 Sep 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:29

**US3022291**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Shanice Bennett (b) (4)	16 Sep 2020 19:29:29

**US3022291**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	16 Sep 2020 19:29:29
	(b) (4)	

**US3022291**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4)	16 Sep 2020 19:29:32
	(b) (4)	

**US3022291**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'I'	(b) (4), (b) (6) System	16 Sep 2020 19:29:32

**US3022291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:45

**US3022291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '14 Sep 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	16 Sep 2020 19:29:45

**US3022291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Shanice Bennett (b) (4)	16 Sep 2020 19:29:45



**US3022291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	16 Sep 2020 19:29:45
	(b) (4)	

**US3022291**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4)	16 Sep 2020 19:29:49

**US3022291**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'I'	(b) (4), (b) (6) System	16 Sep 2020 19:29:49

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:46:45

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:46:45

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:46:45

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'VISIT2'	(b) (4), (b) (6) System	28 Sep 2020 19:46:45

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	28 Sep 2020 19:48:19



US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:48:19

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '12:46'	(b) (4), (b) (6)	28 Sep 2020 19:48:19

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered '28 Sep 2020 12:46'	(b) (4), (b) (6) System	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '36.9' C	(b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:48:19

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:48:19

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '71'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:48:19



**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'bpm'	(b) (4), (b) (6) System	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '16'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'breaths/min'	(b) (4), (b) (6) System	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '102'	(b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'mmHg'	(b) (4), (b) (6) System	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '68'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'mmHg'	(b) (4), (b) (6) System	28 Sep 2020 19:48:19

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	28 Sep 2020 19:50:03



US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:50:03

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '15:04'	(b) (4), (b) (6)	28 Sep 2020 19:50:03

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered '28 Sep 2020 15:04'	(b) (4), (b) (6) System	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '36.5' C	(b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:50:03

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:50:03

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '65'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:50:03



US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'bpm'	(b) (4), (b) (6) System	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '14'	(b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'breaths/min'	(b) (4), (b) (6) System	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '104'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'mmHg'	(b) (4), (b) (6) System	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '63'	(b) (4), (b) (6)	28 Sep 2020 19:50:03

US3022291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'mmHg'	(b) (4), (b) (6) System	28 Sep 2020 19:50:03

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:52:28**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 19:50:17



**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:52:28**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:50:17

US3022291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:52:28

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:50:28

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:50:28

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Urine (URINE)'	(b) (4), (b) (6)	28 Sep 2020 19:50:28

US3022291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:52:28

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	28 Sep 2020 19:50:28

US3022291

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 14:52:28

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 19:50:28

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:50:28

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:50:28



**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered empty.	(b) (4), (b) (6) System	28 Sep 2020 19:50:28

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	28 Sep 2020 18:36:31
	(b) (4)	

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	28 Sep 2020 18:36:31
	(b) (4)	

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered empty.	(b) (4) Chevon Roberts (b) (4)	28 Sep 2020 18:36:31
	(b) (4)	

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '28 Sep 2020'	(b) (4) Chevon Roberts (b) (4)	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '14:34'	Chevon Roberts (b) (4)	28 Sep 2020 18:36:31
	(b) (4)	

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered '28 Sep 2020 14:34'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31



US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Left Arm (LEFT ARM)'	(b) (4) Chevon Roberts (b) (4)	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'ONCE'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:48:40

US3022291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:52:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 19:48:40

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '13:02'	(b) (4), (b) (6)	28 Sep 2020 19:48:40

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered '28 Sep 2020 13:02'	(b) (4), (b) (6) System	28 Sep 2020 19:48:40

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 14:52:28**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:49:13



**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) (b) (4), (b) (6)	28 Sep 2020 19:49:13

US3022291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:52:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:49:13

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '13:24'	(b) (4), (b) (6)	28 Sep 2020 19:49:13

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered '28 Sep 2020 13:24'	(b) (4), (b) (6) System	28 Sep 2020 19:49:13

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) (b) (4), (b) (6)	28 Sep 2020 19:49:13

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:49:13

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 19:49:13

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered empty.	(b) (4), (b) (6) System	28 Sep 2020 19:49:13



US3022291

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 19:49:30

**US3022291**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered '1'	(b) (4), (b) (6) System	28 Sep 2020 19:49:30

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:02:43', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '72997b46-fa8e-409b-9e5a-0af7fd96d2e5'	(b) (4), (b) (6)	
	System	28 Sep 2020 19:02:56
User entered 'Yes (Y)'	System	28 Sep 2020 19:02:56

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:02:47', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '72997b46-fa8e-409b-9e5a-0af7fd96d2e5' User entered '97.7'	(b) (4), (b) (6) System	28 Sep 2020 19:02:56
	System	28 Sep 2020 19:02:56

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:02:51', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '72997b46-fa8e-409b-9e5a-0af7fd96d2e5'	(b) (4), (b) (6)	
	System	28 Sep 2020 19:02:56
User entered 'No (N)'	System	28 Sep 2020 19:02:56

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:02:54', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '72997b46-fa8e-409b-9e5a-0af7fd96d2e5'	(b) (4), (b) (6) System	28 Sep 2020 19:02:56
User entered '28 Sep 2020 15:02'	System	28 Sep 2020 19:02:56

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Sep 2020 14:54'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31



**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Sep 2020 17:24'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:19', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '070660d4-a9d3-4afc-9be8-9db6d8dbcc80' User entered 'Yes (Y)'	System	29 Sep 2020 12:18:34
	System	29 Sep 2020 12:18:34

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:24', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '070660d4-a9d3-4afc-9be8-9db6d8dbcc80' User entered '96.6'	(b) (4), (b) (6) System	29 Sep 2020 12:18:34
	System	29 Sep 2020 12:18:34

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:27', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '070660d4-a9d3-4afc-9be8-9db6d8dbcc80' User entered 'No (N)'	System	29 Sep 2020 12:18:34
	System	29 Sep 2020 12:18:34

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '070660d4-a9d3-4afc-9be8-9db6d8dbcc80' User entered '29 Sep 2020 08:18'	System	29 Sep 2020 12:18:34
	System	29 Sep 2020 12:18:34

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Sep 2020 18:19'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31



US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 2'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:01:40', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f2aecbc8-381a-4eee-adca-43624fc54da1' User entered 'Yes (Y)'	System	30 Sep 2020 04:01:57
	System	30 Sep 2020 04:01:57

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:01:44', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f2aecbc8-381a-4eee-adca-43624fc54da1' User entered '97.4'	System	30 Sep 2020 04:01:57
	System	30 Sep 2020 04:01:57

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:01:49', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f2aecbc8-381a-4eee-adca-43624fc54da1' User entered 'No (N)'	System	30 Sep 2020 04:01:57
	System	30 Sep 2020 04:01:57

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:52:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:01:52', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f2aecbc8-381a-4eee-adca-43624fc54da1' User entered '30 Sep 2020 00:01'	System	30 Sep 2020 04:01:57
	System	30 Sep 2020 04:01:57

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:52:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 3'	System	28 Sep 2020 18:36:31



US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:52:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:52:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31



US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 4'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-01T23:59:52', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cad97df-1696-46f4-9ba9-40fa7cf21a91' User entered 'Yes (Y)'	System	02 Oct 2020 16:13:04
	System	02 Oct 2020 16:13:04

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-01T23:59:56', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cad97df-1696-46f4-9ba9-40fa7cf21a91' User entered '97.5'	(b) (4), (b) (6) System	02 Oct 2020 16:13:04
	System	02 Oct 2020 16:13:04

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:01', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cad97df-1696-46f4-9ba9-40fa7cf21a91'	(b) (4), (b) (6)	
	System	02 Oct 2020 16:13:04
User entered 'No (N)'	System	02 Oct 2020 16:13:04

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:04', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '4cad97df-1696-46f4-9ba9-40fa7cf21a91' User entered '02 Oct 2020 00:00'	System	02 Oct 2020 16:13:04
	System	02 Oct 2020 16:13:04

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:52:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '01 Oct 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:52:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 5'	System	28 Sep 2020 18:36:31



US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:04', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8137e5c0-10d3-4e39-b0ee-08eb9867f89c'	(b) (4), (b) (6)	
	System	02 Oct 2020 16:13:21
User entered 'Yes (Y)'	System	02 Oct 2020 16:13:21

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:08', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8137e5c0-10d3-4e39-b0ee-08eb9867f89c' User entered '96.4'	(b) (4), (b) (6) System	02 Oct 2020 16:13:21
	System	02 Oct 2020 16:13:21

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:16', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8137e5c0-10d3-4e39-b0ee-08eb9867f89c'	(b) (4), (b) (6)	
	System	02 Oct 2020 16:13:21
User entered 'No (N)'	System	02 Oct 2020 16:13:21

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:18', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8137e5c0-10d3-4e39-b0ee-08eb9867f89c' User entered '02 Oct 2020 12:13'	(b) (4), (b) (6) System	02 Oct 2020 16:13:21
	System	02 Oct 2020 16:13:21

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '02 Oct 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '03 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 6'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:03:19', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f72e2207-9e3f-4f83-86f1-8d906b50b296'	(b) (4), (b) (6)	
	System	03 Oct 2020 23:03:38
User entered 'Yes (Y)'	System	03 Oct 2020 23:03:38



US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:03:25', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f72e2207-9e3f-4f83-86f1-8d906b50b296' User entered '97.3'	(b) (4), (b) (6) System	03 Oct 2020 23:03:38
	System	03 Oct 2020 23:03:38

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:03:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f72e2207-9e3f-4f83-86f1-8d906b50b296'	(b) (4), (b) (6)	
	System	03 Oct 2020 23:03:38
User entered 'No (N)'	System	03 Oct 2020 23:03:38

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:03:33', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'f72e2207-9e3f-4f83-86f1-8d906b50b296' User entered '03 Oct 2020 19:03'	System	03 Oct 2020 23:03:38
	System	03 Oct 2020 23:03:38

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:52:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '03 Oct 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '04 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 7'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:52:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:40:41', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '05f17b9d-1661-4f74-929f-023e40576067'	(b) (4), (b) (6)	
	System	05 Oct 2020 14:41:01
User entered 'Yes (Y)'	System	05 Oct 2020 14:41:01

US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:52:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:40:46', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '05f17b9d-1661-4f74-929f-023e40576067' User entered '97.4'	(b) (4), (b) (6) System	05 Oct 2020 14:41:01
	System	05 Oct 2020 14:41:01



US3022291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:40:54', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '05f17b9d-1661-4f74-929f-023e40576067'	(b) (4), (b) (6)	
	System	05 Oct 2020 14:41:01
User entered 'No (N)'	System	05 Oct 2020 14:41:01

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:40:57', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '05f17b9d-1661-4f74-929f-023e40576067' User entered '05 Oct 2020 09:40'	(b) (4), (b) (6) System	05 Oct 2020 14:41:01
	System	05 Oct 2020 14:41:01

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '04 Oct 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '05 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:06', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0f1205b3-8996-467c-9f7b-fcd0459e9e79'	(b) (4), (b) (6) System	28 Sep 2020 19:03:42
User entered 'None (1)'	System	28 Sep 2020 19:03:42

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:28', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0f1205b3-8996-467c-9f7b-fcd0459e9e79'	(b) (4), (b) (6) System	28 Sep 2020 19:03:42
User entered 'No (N)'	System	28 Sep 2020 19:03:42

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:31', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0f1205b3-8996-467c-9f7b-fcd0459e9e79' User entered 'No (N)'	System	28 Sep 2020 19:03:42
	System	28 Sep 2020 19:03:42



US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:36', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0f1205b3-8996-467c-9f7b-fcd0459e9e79'	(b) (4), (b) (6) System	28 Sep 2020 19:03:42
User entered 'None (1)'	System	28 Sep 2020 19:03:42

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:40', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0f1205b3-8996-467c-9f7b-fcd0459e9e79' User entered '28 Sep 2020 15:03'	System	28 Sep 2020 19:03:42
	System	28 Sep 2020 19:03:42

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Sep 2020 14:54'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Sep 2020 17:24'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:38', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '528eef98-2c2e-4eea-9a18-6efe985efd2a'	(b) (4), (b) (6)	
User entered 'None (1)'	System	29 Sep 2020 12:18:54

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:41', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '528eef98-2c2e-4eea-9a18-6efe985efd2a' User entered 'No (N)'	System	29 Sep 2020 12:18:54
	System	29 Sep 2020 12:18:54

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:43', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '528eef98-2c2e-4eea-9a18-6efe985efd2a' User entered 'No (N)'	System	29 Sep 2020 12:18:54
	System	29 Sep 2020 12:18:54



US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:46', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '528eef98-2c2e-4eea-9a18-6efe985efd2a'	System	29 Sep 2020 12:18:54
User entered 'None (1)'	System	29 Sep 2020 12:18:54

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:51', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '528eef98-2c2e-4eea-9a18-6efe985efd2a' User entered '29 Sep 2020 08:18'	System	29 Sep 2020 12:18:54
	System	29 Sep 2020 12:18:54

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Sep 2020 18:19'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 2'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '61a6e18b-6c43-4d77-9c13-2e90ddcd94'	(b) (4), (b) (6)	
	System	30 Sep 2020 04:02:16
User entered 'None (1)'	System	30 Sep 2020 04:02:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:52:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:04', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '61a6e18b-6c43-4d77-9c13-2e90ddcd94'	(b) (4), (b) (6)	
System		30 Sep 2020 04:02:16
User entered 'No (N)'	System	30 Sep 2020 04:02:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:07', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '61a6e18b-6c43-4d77-9c13-2e90ddcd94'	(b) (4), (b) (6) System	30 Sep 2020 04:02:16
User entered 'No (N)'	System	30 Sep 2020 04:02:16



US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:10', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '61a6e18b-6c43-4d77-9c13-2e90ddcd94'	(b) (4), (b) (6)	
	System	30 Sep 2020 04:02:16
User entered 'None (1)'	System	30 Sep 2020 04:02:16

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:13', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '61a6e18b-6c43-4d77-9c13-2e90ddcd94'	(b) (4), (b) (6) System	30 Sep 2020 04:02:16
User entered '30 Sep 2020 00:02'	System	30 Sep 2020 04:02:16

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 3'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:52:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20



US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 4'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:08', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fcf777d2-3536-4469-ab1f-94900d4602b5'	(b) (4), (b) (6) System	02 Oct 2020 16:13:05
User entered 'None (1)'	System	02 Oct 2020 16:13:05



US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:52:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:13', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fcf777d2-3536-4469-ab1f-94900d4602b5' User entered 'No (N)'	System	02 Oct 2020 16:13:05
	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:16', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fcf777d2-3536-4469-ab1f-94900d4602b5' User entered 'No (N)'	System	02 Oct 2020 16:13:05
	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:22', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fcf777d2-3536-4469-ab1f-94900d4602b5'	(b) (4), (b) (6) System	02 Oct 2020 16:13:05
User entered 'None (1)'	System	02 Oct 2020 16:13:05

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:25', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'fcf777d2-3536-4469-ab1f-94900d4602b5' User entered '02 Oct 2020 00:00'	System	02 Oct 2020 16:13:05
	System	02 Oct 2020 16:13:05

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '01 Oct 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 5'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:30', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '142c80c6-c305-44bf-b69e-7a7bcac4d38e'	(b) (4), (b) (6)	
	System	02 Oct 2020 16:13:57
User entered 'None (1)'	System	02 Oct 2020 16:13:57



US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:52:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:38', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '142c80c6-c305-44bf-b69e-7a7bcac4d38e' User entered 'No (N)'	System	02 Oct 2020 16:13:57
	System	02 Oct 2020 16:13:57

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:46', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '142c80c6-c305-44bf-b69e-7a7bcac4d38e' User entered 'No (N)'	System	02 Oct 2020 16:13:57
	System	02 Oct 2020 16:13:57

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:52', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '142c80c6-c305-44bf-b69e-7a7bcac4d38e' User entered 'None (1)'	System	02 Oct 2020 16:13:57
	System	02 Oct 2020 16:13:57

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:13:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '142c80c6-c305-44bf-b69e-7a7bcac4d38e' User entered '02 Oct 2020 12:13'	System	02 Oct 2020 16:13:57
	System	02 Oct 2020 16:13:57

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '02 Oct 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '03 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 6'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:09', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'c21e8dbf-e61e-489b-8ef1-cc16f41ef02e'	(b) (4), (b) (6) System	03 Oct 2020 23:04:44
User entered 'None (1)'	System	03 Oct 2020 23:04:44



US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:14', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'c21e8dbf-e61e-489b-8ef1-cc16f41ef02e' User entered 'No (N)'	System	03 Oct 2020 23:04:44
	System	03 Oct 2020 23:04:44

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:17', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'c21e8dbf-e61e-489b-8ef1-cc16f41ef02e' User entered 'No (N)'	System	03 Oct 2020 23:04:44
	System	03 Oct 2020 23:04:44

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:20', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'c21e8dbf-e61e-489b-8ef1-cc16f41ef02e'	(b) (4), (b) (6)	03 Oct 2020 23:04:44
User entered 'None (1)'	System	03 Oct 2020 23:04:44

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:23', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'c21e8dbf-e61e-489b-8ef1-cc16f41ef02e' User entered '03 Oct 2020 19:04'	(b) (4), (b) (6) System	03 Oct 2020 23:04:44
	System	03 Oct 2020 23:04:44

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '03 Oct 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:52:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '04 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 7'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:01', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dafe8ed1-796f-4193-b311-ea78cc425ef8'	(b) (4), (b) (6) System	05 Oct 2020 14:41:16
User entered 'None (1)'	System	05 Oct 2020 14:41:16



US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:05', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dafe8ed1-796f-4193-b311-ea78cc425ef8' User entered 'No (N)'	System	05 Oct 2020 14:41:16
	System	05 Oct 2020 14:41:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:07', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dafe8ed1-796f-4193-b311-ea78cc425ef8'	(b) (4), (b) (6) System	05 Oct 2020 14:41:16
User entered 'No (N)'	System	05 Oct 2020 14:41:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:09', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dafe8ed1-796f-4193-b311-ea78cc425ef8'	(b) (4), (b) (6) System	05 Oct 2020 14:41:16
User entered 'None (1)'	System	05 Oct 2020 14:41:16

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:11', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dafe8ed1-796f-4193-b311-ea78cc425ef8' User entered '05 Oct 2020 09:41'	System	05 Oct 2020 14:41:16
	System	05 Oct 2020 14:41:16

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '04 Oct 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:52:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '05 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6' User entered 'None (0)'	System	28 Sep 2020 19:04:06
	System	28 Sep 2020 19:04:06



US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:49', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6' User entered 'None (0)'	System	28 Sep 2020 19:04:06
	System	28 Sep 2020 19:04:06

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:51', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6' User entered 'None (0)'	System	28 Sep 2020 19:04:06
	System	28 Sep 2020 19:04:06

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:53', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6' User entered 'None (0)'	System	28 Sep 2020 19:04:06
	System	28 Sep 2020 19:04:06

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6' User entered 'None (0)'	System	28 Sep 2020 19:04:06
	System	28 Sep 2020 19:04:06

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:57', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6'	System	28 Sep 2020 19:04:06
User entered 'None (0)'	System	28 Sep 2020 19:04:06

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:03:59', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6'	(b) (4), (b) (6)	
	System	28 Sep 2020 19:04:06
User entered 'No (N)'	System	28 Sep 2020 19:04:06

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-28T15:04:01', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '7a477a84-7082-4acd-be77-0099d0a1c3f6' User entered '28 Sep 2020 15:04'	(b) (4), (b) (6) System	28 Sep 2020 19:04:06
	System	28 Sep 2020 19:04:06

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Sep 2020 14:54'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31



**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Sep 2020 17:24'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7' User entered 'None (0)'	System	29 Sep 2020 12:19:15
	System	29 Sep 2020 12:19:15

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:56', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7' User entered 'None (0)'	System	29 Sep 2020 12:19:15
	System	29 Sep 2020 12:19:15

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:18:59', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7'	(b) (4), (b) (6)	
User entered 'None (0)'	System	29 Sep 2020 12:19:15

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:19:01', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7' User entered 'None (0)'	System	29 Sep 2020 12:19:15
	System	29 Sep 2020 12:19:15

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:19:02', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7' User entered 'None (0)'	System	29 Sep 2020 12:19:15
	System	29 Sep 2020 12:19:15

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:19:04', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7'	(b) (4), (b) (6)	
	System	29 Sep 2020 12:19:15
User entered 'None (0)'	System	29 Sep 2020 12:19:15



US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:19:08', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7'	(b) (4), (b) (6)	
	System	29 Sep 2020 12:19:15
User entered 'No (N)'	System	29 Sep 2020 12:19:15

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-29T08:19:11', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e4cf4b6f-feae-4dd0-842f-5f3e645fc1a7'	(b) (4), (b) (6)	
	System	29 Sep 2020 12:19:15
User entered '29 Sep 2020 08:19'	System	29 Sep 2020 12:19:15

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '28 Sep 2020 18:19'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 2'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:19', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec' User entered 'None (0)'	System	30 Sep 2020 04:13:30
	System	30 Sep 2020 04:13:30

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:22', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec' User entered 'None (0)'	System	30 Sep 2020 04:13:30
	System	30 Sep 2020 04:13:30

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:24', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec' User entered 'None (0)'	System	30 Sep 2020 04:13:30
	System	30 Sep 2020 04:13:30



US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:26', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec' User entered 'None (0)'	System	30 Sep 2020 04:13:30
	System	30 Sep 2020 04:13:30

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec' User entered 'None (0)'	System	30 Sep 2020 04:13:30
	System	30 Sep 2020 04:13:30

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:02:32', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec' User entered 'None (0)'	System	30 Sep 2020 04:13:30
	System	30 Sep 2020 04:13:30

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:13:24', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec' User entered 'No (N)'	System	30 Sep 2020 04:13:30
	System	30 Sep 2020 04:13:30

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-09-30T00:13:26', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'cc860e2b-9879-4614-ade9-fac38182efec' User entered '30 Sep 2020 00:13'	(b) (4), (b) (6) System	30 Sep 2020 04:13:30
	System	30 Sep 2020 04:13:30

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 3'	System	28 Sep 2020 18:36:31



US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 22:15:20



**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 4'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:33', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55' User entered 'None (0)'	System	02 Oct 2020 16:13:05
	System	02 Oct 2020 16:13:05

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55' User entered 'None (0)'	System	02 Oct 2020 16:13:05
	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:39', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55' User entered 'None (0)'	System	02 Oct 2020 16:13:05
	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:41', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55' User entered 'None (0)'	System	02 Oct 2020 16:13:05
	System	02 Oct 2020 16:13:05

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:43', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55' User entered 'None (0)'	System	02 Oct 2020 16:13:05
	System	02 Oct 2020 16:13:05



**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55' User entered 'None (0)'	System	02 Oct 2020 16:13:05
	System	02 Oct 2020 16:13:05

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:48', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55'	(b) (4), (b) (6)	
	System	02 Oct 2020 16:13:05
User entered 'No (N)'	System	02 Oct 2020 16:13:05

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T00:00:51', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ddc73048-66e1-44db-aa5a-527c054d6e55' User entered '02 Oct 2020 00:00'	System	02 Oct 2020 16:13:05
	System	02 Oct 2020 16:13:05

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '01 Oct 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 5'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:14:06', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4' User entered 'None (0)'	System	02 Oct 2020 16:15:12
	System	02 Oct 2020 16:15:12

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:14:09', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4' User entered 'None (0)'	System	02 Oct 2020 16:15:12
	System	02 Oct 2020 16:15:12



US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:14:13', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4' User entered 'None (0)'	System	02 Oct 2020 16:15:12
	System	02 Oct 2020 16:15:12

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:14:16', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4' User entered 'None (0)'	System	02 Oct 2020 16:15:12
	System	02 Oct 2020 16:15:12

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:14:31', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4' User entered 'None (0)'	System	02 Oct 2020 16:15:12
	System	02 Oct 2020 16:15:12

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:14:36', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4' User entered 'None (0)'	System	02 Oct 2020 16:15:12
	System	02 Oct 2020 16:15:12

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:15:06', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4' User entered 'No (N)'	System	02 Oct 2020 16:15:12
	System	02 Oct 2020 16:15:12

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-02T12:15:10', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '3bba89a5-3ad3-4436-8268-6f66f7e9afd4' User entered '02 Oct 2020 12:15'	System	02 Oct 2020 16:15:12
	System	02 Oct 2020 16:15:12

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '02 Oct 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '03 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31



**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 6'	System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:27', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833' User entered 'None (0)'	System	03 Oct 2020 23:04:51
	System	03 Oct 2020 23:04:51

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833' User entered 'None (0)'	System	03 Oct 2020 23:04:51
	System	03 Oct 2020 23:04:51

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:31', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833' User entered 'None (0)'	System	03 Oct 2020 23:04:51
	System	03 Oct 2020 23:04:51

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:33', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833' User entered 'None (0)'	System	03 Oct 2020 23:04:51
	System	03 Oct 2020 23:04:51

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:38', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833' User entered 'None (0)'	System	03 Oct 2020 23:04:51
	System	03 Oct 2020 23:04:51

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:40', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833' User entered 'None (0)'	System	03 Oct 2020 23:04:51
	System	03 Oct 2020 23:04:51

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:42', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833' User entered 'No (N)'	System	03 Oct 2020 23:04:51
	System	03 Oct 2020 23:04:51



**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-03T19:04:44', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '53e10650-92e6-4835-a614-030c59f21833' User entered '03 Oct 2020 19:04'	System	03 Oct 2020 23:04:51
	System	03 Oct 2020 23:04:51

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '03 Oct 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '04 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	28 Sep 2020 18:36:31
User entered 'Day 7'	System	28 Sep 2020 18:36:31

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:14', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef' User entered 'None (0)'	System	05 Oct 2020 14:41:32
	System	05 Oct 2020 14:41:32

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:16', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef' User entered 'None (0)'	System	05 Oct 2020 14:41:32
	System	05 Oct 2020 14:41:32

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:17', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef' User entered 'None (0)'	System	05 Oct 2020 14:41:32
	System	05 Oct 2020 14:41:32

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:19', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef' User entered 'None (0)'	System	05 Oct 2020 14:41:32
	System	05 Oct 2020 14:41:32



US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:20', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef' User entered 'None (0)'	System	05 Oct 2020 14:41:32
	System	05 Oct 2020 14:41:32

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:22', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef' User entered 'None (0)'	System	05 Oct 2020 14:41:32
	System	05 Oct 2020 14:41:32

US3022291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:25', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef' User entered 'No (N)'	System	05 Oct 2020 14:41:32
	System	05 Oct 2020 14:41:32

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-05T09:41:29', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'aebdfcb6-6a5f-46e7-8c25-b7514f252aef' User entered '05 Oct 2020 09:41'	(b) (4), (b) (6) System	05 Oct 2020 14:41:32
	System	05 Oct 2020 14:41:32

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '04 Oct 2020 12:00'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:52:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
User entered '05 Oct 2020 11:59'	(b) (4), (b) (6) System	28 Sep 2020 18:36:31

**US3022291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:40:31

**US3022291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '05 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:40:31



**US3022291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 19:40:31

**US3022291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 19:40:31

**US3022291**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 19:40:37

**US3022291**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'I'	(b) (4), (b) (6) System	05 Oct 2020 19:40:37

**US3022291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:26:02

**US3022291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:26:02

**US3022291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:26:02

**US3022291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:26:02



**US3022291**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:50:58

**US3022291**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'I'	(b) (4), (b) (6) System	12 Oct 2020 18:50:58

**US3022291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:26:23

**US3022291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:26:23

**US3022291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:26:23

**US3022291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 14:26:23

**US3022291**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:27:10

**US3022291**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'I'	(b) (4), (b) (6) System	19 Oct 2020 14:27:10



**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:35:18

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:35:18

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:35:18

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'VISIT3'	(b) (4), (b) (6) System	23 Oct 2020 18:35:18

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:36:55

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:36:55

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '08:24'	(b) (4), (b) (6)	23 Oct 2020 18:36:55

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered '23 Oct 2020 08:24'	(b) (4), (b) (6) System	23 Oct 2020 18:36:55



**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '36.8' C	(b) (4), (b) (6)	23 Oct 2020 18:36:55

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:36:55

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:36:55

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '64'	(b) (4), (b) (6)	23 Oct 2020 18:36:55

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'bpm'	(b) (4), (b) (6) System	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '16'	(b) (4), (b) (6)	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'breaths/min'	(b) (4), (b) (6) System	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '100'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:36:55



US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'mmHg'	(b) (4), (b) (6) System	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '74'	(b) (4), (b) (6)	23 Oct 2020 18:36:55

US3022291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'mmHg'	(b) (4), (b) (6) System	23 Oct 2020 18:36:55

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:52:28**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 18:37:37

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:52:28**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:37:37

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:38:01



**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:38:01

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '08:39'	(b) (4), (b) (6)	23 Oct 2020 18:38:01

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered '23 Oct 2020 08:39'	(b) (4), (b) (6) System	23 Oct 2020 18:38:01

US3022291

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:52:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:38:15

**US3022291**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'I'	(b) (4), (b) (6) System	23 Oct 2020 18:38:15

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 64'	System	24 Aug 2020 14:49:01

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-24T00:47:49', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '57e2d337-f23e-434a-902c-54cf5bbfab08'	(b) (4), (b) (6)	24 Oct 2020 04:47:59
User entered 'No (N)'	System	24 Oct 2020 04:47:59

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-24T00:47:52', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '57e2d337-f23e-434a-902c-54cf5bbfab08'	(b) (4), (b) (6)	
	System	24 Oct 2020 04:47:59
User entered 'No (N)'	System	24 Oct 2020 04:47:59



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-24T00:47:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '57e2d337-f23e-434a-902c-54cf5bbfab08' User entered '24 Oct 2020 00:47:55'	System	24 Oct 2020 04:47:59
	System	24 Oct 2020 04:47:59

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 14:49:01

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 14:49:01

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 71'	System	24 Aug 2020 14:49:01

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-31T00:02:04', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '34f8cbbe-cca1-4dc8-9273-6d2a62cc9383' User entered 'No (N)'	(b) (4), (b) (6) System	31 Oct 2020 04:02:19
	System	31 Oct 2020 04:02:19

US3022291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:52:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-31T00:02:06', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '34f8cbbe-cca1-4dc8-9273-6d2a62cc9383'	(b) (4), (b) (6)	
	System	31 Oct 2020 04:02:19
User entered 'No (N)'	System	31 Oct 2020 04:02:19

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-10-31T00:02:11', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '34f8cbbe-cca1-4dc8-9273-6d2a62cc9383' User entered '31 Oct 2020 00:02:11'	(b) (4), (b) (6) System	31 Oct 2020 04:02:19
	System	31 Oct 2020 04:02:19

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 14:49:01



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 14:49:01

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered 'Day 78'	System	24 Aug 2020 14:49:01

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-11-07T00:02:15', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '204548c4-9e5f-48bd-af25-daf094a9f98b' User entered 'No (N)'	(b) (4), (b) (6) System	07 Nov 2020 05:02:27
	System	07 Nov 2020 05:02:27

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-11-07T00:02:20', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '204548c4-9e5f-48bd-af25-daf094a9f98b'	(b) (4), (b) (6)	07 Nov 2020 05:02:27
User entered 'No (N)'	System	07 Nov 2020 05:02:27

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-11-07T00:02:25', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '204548c4-9e5f-48bd-af25-daf094a9f98b' User entered '07 Nov 2020 00:02:25'	(b) (4), (b) (6) System	07 Nov 2020 05:02:27
	System	07 Nov 2020 05:02:27

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 14:49:01

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:15:20
Data entry locked.	(b) (4), (b) (6)	
	System	24 Aug 2020 14:49:01
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 14:49:01

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:32:47



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-11-25T03:49:13', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '83824ee1-b0c3-42ed-ba4f-c8ad7ac846c1' User entered 'No (N)'	System	25 Nov 2020 09:49:22
	System	25 Nov 2020 09:49:22

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-11-25T03:49:16', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '83824ee1-b0c3-42ed-ba4f-c8ad7ac846c1' User entered 'No (N)'	System	25 Nov 2020 09:49:22
	System	25 Nov 2020 09:49:22

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-11-25T03:49:20', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '83824ee1-b0c3-42ed-ba4f-c8ad7ac846c1' User entered '25 Nov 2020 03:49:20'	System	25 Nov 2020 09:49:22
	System	25 Nov 2020 09:49:22

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-02T00:34:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '02d2722c-6181-4b47-9d63-e615de611b12'	System	02 Dec 2020 06:34:49
User entered 'No (N)'	System	02 Dec 2020 06:34:49

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-02T00:34:41', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '02d2722c-6181-4b47-9d63-e615de611b12'	System	02 Dec 2020 06:34:49
User entered 'No (N)'	System	02 Dec 2020 06:34:49

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-02T00:34:45', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '02d2722c-6181-4b47-9d63-e615de611b12'	System	02 Dec 2020 06:34:49
User entered '02 Dec 2020 00:34:45'	System	02 Dec 2020 06:34:49

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-11T12:01:41', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'afc238ad-c462-4c7a-a7db-bd26c55fb911'	System	11 Dec 2020 18:01:51
User entered 'No (N)'	System	11 Dec 2020 18:01:51



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-11T12:01:44', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'afc238ad-c462-4c7a-a7db-bd26c55fb911' User entered 'No (N)'	System	11 Dec 2020 18:01:51
	System	11 Dec 2020 18:01:51

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-11T12:01:47', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'afc238ad-c462-4c7a-a7db-bd26c55fb911' User entered '11 Dec 2020 12:01:47'	System	11 Dec 2020 18:01:51
	System	11 Dec 2020 18:01:51

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-16T00:01:25', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '46940c7b-ee36-46d8-8468-081475f569eb' User entered 'No (N)'	System	16 Dec 2020 06:01:54
	System	16 Dec 2020 06:01:54

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-16T00:01:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '46940c7b-ee36-46d8-8468-081475f569eb' User entered 'No (N)'	System	16 Dec 2020 06:01:54
	System	16 Dec 2020 06:01:54

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-16T00:01:43', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '46940c7b-ee36-46d8-8468-081475f569eb' User entered '16 Dec 2020 00:01:43'	System	16 Dec 2020 06:01:54
	System	16 Dec 2020 06:01:54



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-23T09:01:50', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8a262901-0295-4288-8725-d981637cb6f8'	System	23 Dec 2020 15:02:00
User entered 'No (N)'	System	23 Dec 2020 15:02:00

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-23T09:01:54', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8a262901-0295-4288-8725-d981637cb6f8'	System	23 Dec 2020 15:02:00
User entered 'No (N)'	System	23 Dec 2020 15:02:00

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-23T09:01:57', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '8a262901-0295-4288-8725-d981637cb6f8'	System	23 Dec 2020 15:02:00
User entered '23 Dec 2020 09:01:57'	System	23 Dec 2020 15:02:00

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-30T00:01:31', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '6ff8b4c1-27de-4c64-80cd-8f9b4bb95441'	System	30 Dec 2020 06:01:43
User entered 'No (N)'	System	30 Dec 2020 06:01:43

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-30T00:01:33', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '6ff8b4c1-27de-4c64-80cd-8f9b4bb95441'	System	30 Dec 2020 06:01:43
User entered 'No (N)'	System	30 Dec 2020 06:01:43

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2020-12-30T00:01:37', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '6ff8b4c1-27de-4c64-80cd-8f9b4bb95441' User entered '30 Dec 2020 00:01:37'	System	30 Dec 2020 06:01:43
	System	30 Dec 2020 06:01:43

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-01-06T00:16:48', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0ba61108-9a12-4e9b-9dfc-8b8197e4f16f' User entered 'No (N)'	System	06 Jan 2021 06:16:58
	System	06 Jan 2021 06:16:58



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-01-06T00:16:50', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0ba61108-9a12-4e9b-9dfc-8b8197e4f16f' User entered 'No (N)'	System	06 Jan 2021 06:16:58
	System	06 Jan 2021 06:16:58

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-01-06T00:16:53', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '0ba61108-9a12-4e9b-9dfc-8b8197e4f16f' User entered '06 Jan 2021 00:16:53'	System	06 Jan 2021 06:16:58
	System	06 Jan 2021 06:16:58

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-01-14T11:06:26', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '86178b93-1bdb-4547-8205-292a2c62cddb' User entered 'No (N)'	System	14 Jan 2021 16:06:39
	System	14 Jan 2021 16:06:39

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-01-14T11:06:30', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '86178b93-1bdb-4547-8205-292a2c62cddb'	System	14 Jan 2021 16:06:39
User entered 'No (N)'	System	14 Jan 2021 16:06:39

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-01-14T11:06:34', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '86178b93-1bdb-4547-8205-292a2c62cddb' User entered '14 Jan 2021 11:06:34'	System	14 Jan 2021 16:06:39



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-01-20T00:02:21', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e76eebdc-5bae-4b89-93ba-4f641aeac7dc'	System	20 Jan 2021 05:02:41
User entered 'No (N)'	System	20 Jan 2021 05:02:41

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-01-20T00:02:25', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e76eebdc-5bae-4b89-93ba-4f641aeac7dc'	System	20 Jan 2021 05:02:41
User entered 'No (N)'	System	20 Jan 2021 05:02:41

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-01-20T00:02:27', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'e76eebdc-5bae-4b89-93ba-4f641aeac7dc' User entered '20 Jan 2021 00:02:27'	System	20 Jan 2021 05:02:41
	System	20 Jan 2021 05:02:41

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-01-27T00:01:51', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '50df85a3-f0f7-43f1-bd88-51ff629894af'	System	27 Jan 2021 05:02:30
User entered 'No (N)'	System	27 Jan 2021 05:02:30

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-01-27T00:01:53', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '50df85a3-f0f7-43f1-bd88-51ff629894af'	System	27 Jan 2021 05:02:30
User entered 'No (N)'	System	27 Jan 2021 05:02:30

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-01-27T00:01:58', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '50df85a3-f0f7-43f1-bd88-51ff629894af' User entered '27 Jan 2021 00:01:58'	System	27 Jan 2021 05:02:30

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-02-03T00:07:04', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dc910900-1430-481b-ae56-0c96415cbf99'	System	03 Feb 2021 05:07:13
User entered 'No (N)'	System	03 Feb 2021 05:07:13



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-02-03T00:07:07', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dc910900-1430-481b-ae56-0c96415cbf99'	System	03 Feb 2021 05:07:13
User entered 'No (N)'	System	03 Feb 2021 05:07:13

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-02-03T00:07:10', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dc910900-1430-481b-ae56-0c96415cbf99'	System	03 Feb 2021 05:07:13
User entered '03 Feb 2021 00:07:10'	System	03 Feb 2021 05:07:13

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-02-10T01:28:48', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '44dc0fde-6b10-4fcd-b5cd-274ccd1abb4c' User entered 'No (N)'	System	10 Feb 2021 06:28:58
	System	10 Feb 2021 06:28:58

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-02-10T01:28:51', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '44dc0fde-6b10-4fcd-b5cd-274ccd1abb4c'	System	10 Feb 2021 06:28:58
User entered 'No (N)'	System	10 Feb 2021 06:28:58

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-02-10T01:28:55', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '44dc0fde-6b10-4fcd-b5cd-274ccd1abb4c' User entered '10 Feb 2021 01:28:55'	System	10 Feb 2021 06:28:58
	System	10 Feb 2021 06:28:58



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-02-17T00:41:54', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '5efa20a2-eef0-49ce-9b86-2c60b720ffd0'	System	17 Feb 2021 05:42:04
User entered 'No (N)'	System	17 Feb 2021 05:42:04

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-02-17T00:41:57', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '5efa20a2-eef0-49ce-9b86-2c60b720ffd0'	System	17 Feb 2021 05:42:04
User entered 'No (N)'	System	17 Feb 2021 05:42:04

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-02-17T00:42:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '5efa20a2-eef0-49ce-9b86-2c60b720ffd0' User entered '17 Feb 2021 00:42:00'	System	17 Feb 2021 05:42:04
	System	17 Feb 2021 05:42:04

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-02-24T03:58:48-06:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '69ba0eb6-63dc-40d0-a273-df3e73900f57'	System	24 Feb 2021 09:58:57
User entered 'No (N)'	System	24 Feb 2021 09:58:57

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-02-24T03:58:51-06:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '69ba0eb6-63dc-40d0-a273-df3e73900f57'	System	24 Feb 2021 09:58:57
User entered 'No (N)'	System	24 Feb 2021 09:58:57

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-02-24T03:58:54-06:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '69ba0eb6-63dc-40d0-a273-df3e73900f57'	System	24 Feb 2021 09:58:57
User entered '24 Feb 2021 09:58:54'	System	24 Feb 2021 09:58:57

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-03-03T08:40:03-06:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '96c853ca-b533-4913-a99a-778725f1d3be'	System	03 Mar 2021 14:41:00
User entered 'No (N)'	System	03 Mar 2021 14:41:00



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-03-03T08:40:19-06:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '96c853ca-b533-4913-a99a-778725f1d3be'	System	03 Mar 2021 14:41:00
User entered 'No (N)'	System	03 Mar 2021 14:41:00

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-03-03T08:40:27-06:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '96c853ca-b533-4913-a99a-778725f1d3be' User entered '03 Mar 2021 08:40:27'	System	03 Mar 2021 14:41:00
	System	03 Mar 2021 14:41:00

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-03-10T04:09:13-06:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'eb5a5a25-ab27-4541-b8d3-a6d02111b02f'	System	10 Mar 2021 10:09:26
User entered 'No (N)'	System	10 Mar 2021 10:09:26

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-03-10T04:09:18-06:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'eb5a5a25-ab27-4541-b8d3-a6d02111b02f'	System	10 Mar 2021 10:09:26
User entered 'No (N)'	System	10 Mar 2021 10:09:26

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-03-10T04:09:23-06:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'eb5a5a25-ab27-4541-b8d3-a6d02111b02f' User entered '10 Mar 2021 04:09:23'	System	10 Mar 2021 10:09:26
	System	10 Mar 2021 10:09:26



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-03-19T12:00:26-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'c0a6f541-e521-4803-87b6-e2e961915fee'	System	23 Mar 2021 20:47:32
User entered 'No (N)'	System	23 Mar 2021 20:47:32

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-03-19T12:00:29-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'c0a6f541-e521-4803-87b6-e2e961915fee'	System	23 Mar 2021 20:47:32
User entered 'No (N)'	System	23 Mar 2021 20:47:32

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-03-19T12:00:32-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'c0a6f541-e521-4803-87b6-e2e961915fee' User entered '19 Mar 2021 12:00:32'	System	23 Mar 2021 20:47:32
	System	23 Mar 2021 20:47:32

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-03-26T12:06:09-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ef66e62a-cc43-4f9e-9b69-e77525d67b53'	System	26 Mar 2021 17:07:32
User entered 'No (N)'	System	26 Mar 2021 17:07:32

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-03-26T12:06:12-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ef66e62a-cc43-4f9e-9b69-e77525d67b53'	System	26 Mar 2021 17:07:32
User entered 'No (N)'	System	26 Mar 2021 17:07:32

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-03-26T12:06:15-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'ef66e62a-cc43-4f9e-9b69-e77525d67b53'	System	26 Mar 2021 17:07:32
User entered '26 Mar 2021 12:06:15'	System	26 Mar 2021 17:07:32

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-04T12:01:05-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '82ee16c8-5f3c-4b21-aa5e-26afdfd508b8' User entered 'No (N)'	System	04 Apr 2021 17:02:15
	System	04 Apr 2021 17:02:15



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-04T12:01:10-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '82ee16c8-5f3c-4b21-aa5e-26afdfd508b8'	System	04 Apr 2021 17:02:15
User entered 'No (N)'	System	04 Apr 2021 17:02:15

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-04T12:01:14-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '82ee16c8-5f3c-4b21-aa5e-26afdfd508b8' User entered '04 Apr 2021 12:01:14'	System	04 Apr 2021 17:02:15
	System	04 Apr 2021 17:02:15

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-07T05:12:16-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '14def551-6710-40da-b0ee-6d80824994a5' User entered 'No (N)'	System	07 Apr 2021 10:12:23
	System	07 Apr 2021 10:12:23

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-07T05:12:18-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '14def551-6710-40da-b0ee-6d80824994a5' User entered 'No (N)'	System	07 Apr 2021 10:12:23
	System	07 Apr 2021 10:12:23

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-07T05:12:21-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '14def551-6710-40da-b0ee-6d80824994a5' User entered '07 Apr 2021 05:12:21'	System	07 Apr 2021 10:12:23
	System	07 Apr 2021 10:12:23



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-16T12:00:27-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9aaf767b-5c0b-4b08-ab3f-6d2968df104a'	System	16 Apr 2021 17:00:52
User entered 'No (N)'	System	16 Apr 2021 17:00:52

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-16T12:00:30-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9aaf767b-5c0b-4b08-ab3f-6d2968df104a'	System	16 Apr 2021 17:00:52
User entered 'No (N)'	System	16 Apr 2021 17:00:52

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-16T12:00:33-05:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '9aaf767b-5c0b-4b08-ab3f-6d2968df104a' User entered '16 Apr 2021 12:00:33'	System	16 Apr 2021 17:00:52
	System	16 Apr 2021 17:00:52

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-21T00:03:22-04:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '2e7ac370-bdd6-4472-93a9-318228478c79'	System	21 Apr 2021 04:03:51
User entered 'No (N)'	System	21 Apr 2021 04:03:51

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-21T00:03:25-04:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '2e7ac370-bdd6-4472-93a9-318228478c79'	System	21 Apr 2021 04:03:51
User entered 'No (N)'	System	21 Apr 2021 04:03:51

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-21T00:03:28-04:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '2e7ac370-bdd6-4472-93a9-318228478c79' User entered '21 Apr 2021 00:03:28'	System	21 Apr 2021 04:03:51
	System	21 Apr 2021 04:03:51

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-30T12:00:50-04:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '2db864a0-3ec0-4c79-b418-49f5269a1211' User entered 'No (N)'	System	30 Apr 2021 16:05:01
	System	30 Apr 2021 16:05:01



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

Have you been exposed to someone with 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 (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-30T12:00:53-04:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '2db864a0-3ec0-4c79-b418-49f5269a1211'	System	30 Apr 2021 16:05:01
User entered 'No (N)'	System	30 Apr 2021 16:05:01

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-04-30T12:00:56-04:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: '2db864a0-3ec0-4c79-b418-49f5269a1211'	System	30 Apr 2021 16:05:01
User entered '30 Apr 2021 12:00:56'	System	30 Apr 2021 16:05:01

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:32:47



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:32:47



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:32:47



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:32:47



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:32:47



**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:32:47

**US3022291**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:32:47



**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:32:47

**US3022291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:52:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:32:47
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:32:47

US3022291

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:52:28

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:55:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-03-03T08:40:40-06:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dcd067f2-dc8e-48fc-bbcb-e4cf0af840fc'	System	03 Mar 2021 14:41:13
User entered 'No (N)'	System	03 Mar 2021 14:41:13

**US3022291**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:55:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (39863F1D-DEDA-4ADD-8601-A24FAC22BAC0)', Time: '2021-03-03T08:40:51-06:00', User OID: 'PatientReportedOutcome (US3022291)', ODM File OID: 'dcd067f2-dc8e-48fc-bbcb-e4cf0af840fc' User entered '03 Mar 2021 08:40:51'	System	03 Mar 2021 14:41:13
	System	03 Mar 2021 14:41:13



**US3022291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 20:00:47

**US3022291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 20:00:47

**US3022291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 20:00:47

**US3022291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 20:00:47

**US3022291**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 20:00:51

**US3022291**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:50:06
User entered 'I'	(b) (4), (b) (6) System	28 Dec 2020 20:00:51

**US3022291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 19:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 20:01:03

**US3022291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 19:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 20:01:03



**US3022291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 19:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Dec 2020 20:01:03

**US3022291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 19:00:47
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 20:01:03

**US3022291**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 19:00:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 20:01:23

**US3022291**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 19:00:47
User entered 'I'	(b) (4), (b) (6) System	28 Dec 2020 20:01:23

**US3022291**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 19:00:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 21:28:18

US3022291

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 19:00:47
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 11FEB2021 under Participant Decision Visit / OL-D1 Day 1 in PPD central lab, however same is missing in EDC. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 05:09:57
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 11FEB2021 under Participant Decision Visit / OL-D1 Day 1 in PPD central lab, however same is missing in EDC. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:55:20
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 11FEB2021 under Participant Decision Visit / OL-D1 Day 1 in PPD central lab, however same is missing in EDC. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 05:36:02
User entered '25 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 21:28:18

**US3022291**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 19:00:47
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 21:28:18

US3022291

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:52:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 19:00:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 21:28:18



**US3022291**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 19:00:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 21:28:22

**US3022291**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 19:00:47
User entered 'I'	(b) (4), (b) (6) System	25 Jan 2021 21:28:22

**US3022291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 12:25:19

**US3022291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 12:25:19

**US3022291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 12:25:19

**US3022291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 12:25:19

**US3022291**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 12:25:23

**US3022291**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:47:55
User entered 'I'	System	30 Mar 2021 12:25:23



**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 15:09:33

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '23 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 15:09:33

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Mar 2021 15:09:33

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User entered 'VISIT4'	System	30 Mar 2021 15:09:33

US3022291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User closed query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for Vital signs page and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 19:43:31
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
Query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for Vital signs page and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:27:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:27:21
User opened query 'Per Sponsor Review : Please note Visit 4 D209 and OL-D29 is done on the same date, Data should be same in Part A and Part B for Vital signs page and all the respective pages to be completed, if done on the same day the data should be present in both the pages and should be same. Kindly reconcile and update appropriately. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 07:00:22
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 15:09:55

US3022291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '23 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:27:21
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:09:55

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '15:37' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:27:21
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:09:55

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User entered '23 Mar 2021 15:37'	System	12 Apr 2021 13:27:21
User entered empty.	System	30 Mar 2021 15:09:55



US3022291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '36.7' C reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:27:21
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:09:55

US3022291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:27:21
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:09:55

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:09:55

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '69' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:27:21
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:09:55

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User entered 'bpm'	System	12 Apr 2021 13:27:21
User entered empty.	System	30 Mar 2021 15:09:55

US3022291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:27:21
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:09:55

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User entered 'breaths/min'	System	12 Apr 2021 13:27:21
User entered empty.	System	30 Mar 2021 15:09:55

US3022291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '113' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:27:21
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:09:55



US3022291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User entered 'mmHg'	System	12 Apr 2021 13:27:21
User entered empty.	System	30 Mar 2021 15:09:55

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '84' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:27:21
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 15:09:55

US3022291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User entered 'mmHg'	System	12 Apr 2021 13:27:21
User entered empty.	System	30 Mar 2021 15:09:55

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50

US3022291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50

US3022291

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:52:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 15:10:04

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:52:28**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '23 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 15:10:04

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 15:10:16



**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '23 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 15:10:16

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '15:54'	(b) (4), (b) (6)	30 Mar 2021 15:10:16

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User entered '23 Mar 2021 15:54'	System	30 Mar 2021 15:10:16

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 15:10:28

**US3022291**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:18:50
User entered 'I'	System	30 Mar 2021 15:10:28

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:18:40

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '11 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 18:18:40

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Feb 2021 18:18:40



**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	22 Feb 2021 18:18:40

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:52:28**

**Date of updated informed consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '11 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 18:19:06

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:52:28**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:10:41
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:45:16

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:52:28**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:19:06

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:52:28**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:10:41
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:45:16

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:52:28**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '11 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 18:19:06

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:52:28**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Feb 2021 18:19:06

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:52:28**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Feb 2021 18:19:06



**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:52:28**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	22 Feb 2021 18:19:06

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:52:28**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:19:06

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:52:28**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered '1'	(b) (4), (b) (6) System	22 Feb 2021 18:19:06

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered '1'	(b) (4), (b) (6) System	22 Feb 2021 18:19:06

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:52:28**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:52:28**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:52:28**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User entered empty.	System	22 Feb 2021 18:32:23
DataPoint set to visible.	System	22 Feb 2021 18:19:06

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:52:28**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Feb 2021 18:32:23



**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:52:28**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Feb 2021 18:32:23

US3022291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:52:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User entered empty.	System	22 Feb 2021 18:32:23
DataPoint set to visible.	System	22 Feb 2021 18:19:06

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

US3022291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

US3022291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '11 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '16:35'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered '11 Feb 2021 16:35'	(b) (4), (b) (6) System	22 Feb 2021 18:32:23

US3022291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '36.7' C	(b) (4), (b) (6)	22 Feb 2021 18:32:23



**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '55'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered 'bpm'	(b) (4), (b) (6) System	22 Feb 2021 18:32:23

US3022291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '15'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered 'breaths/min'	(b) (4), (b) (6) System	22 Feb 2021 18:32:23

US3022291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:52:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '124'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered 'mmHg'	(b) (4), (b) (6) System	22 Feb 2021 18:32:23



**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '86'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered 'mmHg'	(b) (4), (b) (6) System	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:52:28**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:52:28**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 14:52:28**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User entered empty.	System	22 Feb 2021 18:32:23
DataPoint set to visible.	System	22 Feb 2021 18:19:06

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '11 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:32:23



**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '17:47'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered '11 Feb 2021 17:47'	(b) (4), (b) (6) System	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '36.8' C	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '64'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered 'bpm'	(b) (4), (b) (6) System	22 Feb 2021 18:32:23

US3022291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '16'	(b) (4), (b) (6)	22 Feb 2021 18:32:23



US3022291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered 'breaths/min'	(b) (4), (b) (6) System	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '135'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered 'mmHg'	(b) (4), (b) (6) System	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '82'	(b) (4), (b) (6)	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered 'mmHg'	(b) (4), (b) (6) System	22 Feb 2021 18:32:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:52:28**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:30:31

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:52:28**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '11 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 18:30:31

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:31:05



**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '11 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 18:31:05

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Urine (URINE)'	(b) (4), (b) (6)	22 Feb 2021 18:31:05

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	22 Feb 2021 18:31:05

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Feb 2021 18:31:05

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 18:31:05

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 18:31:05

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered empty.	(b) (4), (b) (6) System	22 Feb 2021 18:31:05

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:30:23



**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 18:30:23

US3022291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Feb 2021 18:30:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered 'mRNA-1273'	(b) (4), (b) (6)	
	System	22 Feb 2021 18:30:23
DataPoint set to visible.	System	22 Feb 2021 18:19:06

US3022291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '11 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 18:30:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '17:07'	(b) (4), (b) (6)	22 Feb 2021 18:30:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered '11 Feb 2021 17:07'	(b) (4), (b) (6) System	22 Feb 2021 18:30:23

US3022291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	22 Feb 2021 18:30:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered 'ONCE'	(b) (4), (b) (6) System	22 Feb 2021 18:30:23



US3022291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	22 Feb 2021 18:30:23

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:19:24

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '11 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 18:19:24

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '15:45'	(b) (4), (b) (6)	22 Feb 2021 18:19:24

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered '11 Feb 2021 15:45'	(b) (4), (b) (6) System	22 Feb 2021 18:19:24

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:52:28**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:19:35

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '11 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 18:19:35

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered '15:40'	(b) (4), (b) (6)	22 Feb 2021 18:19:35



**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:52:28**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered '11 Feb 2021 15:40'	(b) (4), (b) (6) System	22 Feb 2021 18:19:35

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:19:52

**US3022291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:18:01
User entered '1'	(b) (4), (b) (6) System	22 Feb 2021 18:19:52

**US3022291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:06
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:32:36

**US3022291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:06
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:32:36

**US3022291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:06
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Feb 2021 18:32:36

**US3022291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:06
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:32:36

**US3022291**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:06
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:32:41



**US3022291**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:06
User entered 'I'	System	22 Feb 2021 18:32:41

**US3022291**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:06
User entered '1'	System	22 Feb 2021 18:32:41
DataPoint set to visible.	System	22 Feb 2021 18:32:41

**US3022291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 12:23:31

**US3022291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 12:23:31

**US3022291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Mar 2021 12:23:31

**US3022291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered 'OLD29'	System	30 Mar 2021 12:23:31

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 12:24:08



**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '23 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '15:37'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered '23 Mar 2021 15:37'	System	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '36.9' C	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '69'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered 'bpm'	System	30 Mar 2021 12:24:08



**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '16'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered 'breaths/min'	System	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '113'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered 'mmHg'	System	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '84'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered 'mmHg'	System	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 12:24:08



**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '23 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '17:06'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered '23 Mar 2021 17:06'	System	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '36.8' C	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '76'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered 'bpm'	System	30 Mar 2021 12:24:08



US3022291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '16'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered 'breaths/min'	System	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '104'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered 'mmHg'	System	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '84'	(b) (4), (b) (6)	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered 'mmHg'	System	30 Mar 2021 12:24:08

**US3022291**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:52:28**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 12:24:18

**US3022291**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:52:28**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '23 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 12:24:18



**US3022291**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 12:24:32

**US3022291**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '23 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 12:24:32

**US3022291**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Urine (URINE)'	(b) (4), (b) (6)	30 Mar 2021 12:24:32

**US3022291**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	30 Mar 2021 12:24:32

**US3022291**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 12:24:32

**US3022291**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 12:24:32

**US3022291**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 12:24:32

**US3022291**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered empty.	System	30 Mar 2021 12:24:32



**US3022291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 12:24:41

**US3022291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 12:24:41

US3022291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 12:24:41

**US3022291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered 'mRNA-1273'	System	30 Mar 2021 12:24:41
DataPoint set to visible.	System	22 Feb 2021 18:32:41

**US3022291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '23 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 12:24:41

**US3022291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '16:36'	(b) (4), (b) (6)	30 Mar 2021 12:24:41

**US3022291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered '23 Mar 2021 16:36'	System	30 Mar 2021 12:24:41

**US3022291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:52:28**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	30 Mar 2021 12:24:41



US3022291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered 'ONCE'	System	30 Mar 2021 12:24:41

US3022291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:52:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered 'INTRAMUSCULAR'	System	30 Mar 2021 12:24:41

**US3022291**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 12:24:45

**US3022291**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:47:55
User entered 'I'	System	30 Mar 2021 12:24:45

**US3022291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:14

**US3022291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:14

**US3022291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:14

**US3022291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:52:28**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:14



**US3022291**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:24:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 15:08:18

**US3022291**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:52:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 15:08:18

**US3022291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:17:26

**US3022291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:17:26

**US3022291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:17:26

**US3022291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:52:28**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	22 Apr 2021 14:17:26

**US3022291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:16

**US3022291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:16



**US3022291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '08:27'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:16

**US3022291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Apr 2021 08:27'	System	22 Apr 2021 14:18:16

**US3022291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '37.1' C	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:16

**US3022291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:16

**US3022291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:16

**US3022291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '62'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:16

**US3022291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Apr 2021 14:18:16

US3022291

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:52:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '16'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:16



**US3022291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Apr 2021 14:18:16

**US3022291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '130'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:16

**US3022291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Apr 2021 14:18:16

**US3022291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '86'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:16

**US3022291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:52:28**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Apr 2021 14:18:16

**US3022291**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:52:28**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:23

**US3022291**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:52:28**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:23

**US3022291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:35



**US3022291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:35

**US3022291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '08:38'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:18:35

**US3022291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:52:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Apr 2021 08:38'	System	22 Apr 2021 14:18:35

**US3022291**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 14:52:28**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:59
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 20:40:05
User entered 'No (N)'	Shanice Bennett (b) (4)	16 Sep 2020 19:29:55

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 00:59:48
User entered	System	24 Nov 2020 00:59:42
'USA-US051-2020-mRNA-1273-P301000013'		
User entered 'New'	(b) (4), (b) (6)	24 Nov 2020 00:59:42

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\23.0.	Coder Import (b) (4)	21 Jan 2021 20:13:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	21 Jan 2021 20:13:14
Data point term sent to Coder	System	21 Jan 2021 20:12:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
Data point term sent to Coder	System	03 Dec 2020 16:46:22
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Knee arthritis - version MedDRA\23.0.	Coder Import (b) (4)	21 Nov 2020 09:05:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Nov 2020 09:05:14
Data point term sent to Coder	System	20 Nov 2020 20:43:11
User entered 'Worsening of right knee arthritis'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered 'No (N)'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	



US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered 'No (N)'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered '09 Nov 2020'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered empty.	System	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered 'No (N)'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered '12 Nov 2020'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered empty.	System	20 Nov 2020 20:42:20



US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 20:51:49
User entered 'Grade 3/Severe (Grade 3/Severe)'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
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	20 Nov 2020 20:42:38
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	20 Nov 2020 20:42:20
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered '0'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered '0'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		20 Nov 2020 20:42:38
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		20 Nov 2020 20:42:38
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 20:42:38
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	20 Nov 2020 20:42:20
User entered '0'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered '09 Nov 2020'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

US3022291

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered '12 Nov 2020'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered 'No (N)'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered '0'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered '0'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered '0'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered 'Not Applicable (NOT APPLICABLE)'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered '0'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered 'I'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered 'I'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:50:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User closed query 'PV Query: Did the subject's condition worsen before or after receipt of IP? If before, this would not qualify as a SAE per section 8.3.10 of protocol as it was pre-planned. Please delete event from EDC if condition did not worsen after receipt of IP.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 22:07:36
User closed query 'PV Query: Please clarify treatment medication Alquist. Should this be Eliquis? If not, please provide corrected name or state that is it correct as reported.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 22:07:33
User closed query 'PV Query: Please confirm if any diagnostic imaging was performed. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 22:07:30
Query 'PV Query: Please confirm if any diagnostic imaging was performed. If not done, please state so.' answered with 'there were none received' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 20:15:27
Query 'PV Query: Did the subject's condition worsen before or after receipt of IP? If before, this would not qualify as a SAE per section 8.3.10 of protocol as it was pre-planned. Please delete event from EDC if condition did not worsen after receipt of IP.' answered with 'after IP' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 20:13:34
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
Query 'PV Query: Please clarify treatment medication Alquist. Should this be Eliquis? If not, please provide corrected name or state that is it correct as reported.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 16:44:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:52:28

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Did the subject's condition worsen before or after receipt of IP? If before, this would not qualify as a SAE per section 8.3.10 of protocol as it was pre-planned. Please delete event from EDC if condition did not worsen after receipt of IP.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:18:04
User opened query 'PV Query: Please clarify treatment medication Alquist. Should this be Eliquis? If not, please provide corrected name or state that it is correct as reported.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:17:57
User opened query 'PV Query: Please confirm if any diagnostic imaging was performed. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:17:51
User entered 'Pre-planned surgery for worsening for right knee arthritis that started in un/unk/2019'	Shanice Bennett (b) (4)	20 Nov 2020 20:42:20

**US3022291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered 'I'	System	20 Nov 2020 20:42:20

**US3022291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered 'I'	System	20 Nov 2020 20:42:20



**US3022291**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Jan 2021 20:12:10
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	03 Dec 2020 16:45:23
User entered '0'	System	20 Nov 2020 20:42:20

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 14:52:28**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:59
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 09:53:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 09:53:45
Data point term sent to Coder Coding entries removed.	System Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:08:03 17 Sep 2020 21:07:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:36:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:36:47
Data point term sent to Coder User entered 'Diclofenac'	System Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:12 24 Aug 2020 19:35:46

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User closed query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 06:07:34
Query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'IT IS JUST ARTHRITIS IN THE KNEE' (Site from DM).	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 21:11:01
User opened query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:35:46
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 14:04:13
Query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:07:59
User entered 'right knee ARTHRITIS' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:07:55
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Sep 2020 03:27:54
User entered 'Arthritis'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered '75-200'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:52:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit or the dosage. Reconcile and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:30:02
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit or the dosage. Reconcile and update as appropriate.' answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:08:40
User entered 'mg (mg)' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:08:36
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit or the dosage. Reconcile and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Sep 2020 03:27:35
User entered 'tablet (TABLET)'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46



**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'once daily (QD)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'Oral (ORAL)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'un UNK 2019'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46



**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:35:46

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:35:46

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:35:46

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:35:46

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Sep 2020 21:35:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 21:35:46
Data point term sent to Coder Coding entries removed.	System Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:08:05 17 Sep 2020 21:08:04
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:37:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:37:31
Data point term sent to Coder User entered 'Celecoxib'	System Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:13 24 Aug 2020 19:36:09

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:52:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User closed query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 06:07:49
Query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate' answered with 'IT IS JUST ARTHRITIS IN THE KNEE' (Site from DM).	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 21:11:24
User opened query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:36:15
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	18 Sep 2020 14:04:28
' (Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:08:08
' answered with 'updated' (Site from DM).		
User entered 'right knee ARTHRITIS' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	17 Sep 2020 21:08:04
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	12 Sep 2020 03:28:28
' (Site from DM).		
User entered 'Arthritis'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered '100'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09



**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'mg (mg)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'once daily (QD)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'Oral (ORAL)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'un UNK 2019'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09



**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:09

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:36:09

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:36:09

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:36:09

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: OLMESARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Aug 2020 19:38:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:38:40
Data point term sent to Coder	System	24 Aug 2020 19:37:17
User entered 'Olmesartan'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34



**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'Hypertension'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:52:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User closed query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 21:44:24
User entered '10' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	22 Sep 2020 18:49:58
Query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate. ' answered with 'this dosage is correct ' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	22 Sep 2020 18:49:20
User opened query 'Per DM CLR: Please review the dose of this medication as this is not the standard dose. Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Sep 2020 03:30:50
User entered '12.5'	Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'mg (mg)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'once daily (QD)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'Oral (ORAL)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34



**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'un Jan 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	24 Aug 2020 19:36:34

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:36:34

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 19:36:34

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:52:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 19:36:34



US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Dec 2020 16:46:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Dec 2020 16:46:06
Data point term sent to Coder	System	03 Dec 2020 16:45:21
User closed query 'For coding purposes, The trade name AHLQUIST cannot be referenced in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name, or specify if unknown, and please make your changes to the reported term.' (Site from System).	System	03 Dec 2020 16:44:45
Query 'For coding purposes, The trade name AHLQUIST cannot be referenced in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name, or specify if unknown, and please make your changes to the reported term.' answered with 'UPDATED' (Site from System).	(b) (4), (b) (6)	03 Dec 2020 16:44:45
User entered 'ELIQUIS' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Dec 2020 16:44:40
User opened query 'For coding purposes, The trade name AHLQUIST cannot be referenced in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name, or specify if unknown, and please make your changes to the reported term.' (Site from System).	Coder Import (b) (4)	27 Nov 2020 18:49:12
Data point term sent to Coder	System	25 Nov 2020 20:24:16

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:28

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'CDM-Coding: Please update the term to include the active ingredient name(s) in brackets next to the drug to enable coding. (Site from System).	System	25 Nov 2020 20:23:26
Query 'CDM-Coding: Please update the term to include the active ingredient name(s) in brackets next to the drug to enable coding. answered with 'UPDATED' (Site from System).	Morgan Deal (b) (4) (b) (4)	25 Nov 2020 20:23:26
User entered 'AHLQUIST' reason for change: Per Query Resolution	Morgan Deal (b) (4) (b) (4)	25 Nov 2020 20:23:21
User opened query 'CDM-Coding: Please update the term to include the active ingredient name(s) in brackets next to the drug to enable coding. (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:25:05
Data point term sent to Coder	System	20 Nov 2020 20:44:12
User entered 'ALQUIST'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'No (N)'	Shanice Bennett (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 03:16:45
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:34:45
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'there is an ae that matches thsi' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 19:13:44
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'this is correct' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 19:13:02
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 08:41:49
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 08:41:30

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:28

[Indication](#)

Audit	User	Time (GMT)
User entered 'WORSENING RIGHT KNEE ARTHRITIS'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:43:47

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered '2.5'	Shanice Bennett (b) (4)	20 Nov 2020 20:43:47

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'mg (mg)'	Shanice Bennett (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 20:43:47



**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'twice daily (BID)'	Shanice Bennett (b) (4)	20 Nov 2020 20:43:47

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:52:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 20:43:47

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	20 Nov 2020 20:43:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 20:43:47

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered '09 Nov 2020'	Shanice Bennett (b) (4)	20 Nov 2020 20:43:47

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered '0'	Shanice Bennett (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 11:27:27
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 14:29:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 14:29:32
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 00:38:53
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 14:29:32
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 20:43:47



US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:52:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'No (N)'	Shanice Bennett (b) (4)	20 Nov 2020 20:43:47

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User entered '2'	System	20 Nov 2020 20:43:47

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User entered 'l'	System	20 Nov 2020 20:43:47

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:52:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:25
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:51
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:36
User entered '804 (804)'	System	20 Nov 2020 20:43:47

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 14:41:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 14:41:28
Data point term sent to Coder	System	29 Jan 2021 19:14:37
Coding entries removed.	(b) (4), (b) (6)	29 Jan 2021 19:13:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 09:05:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 09:05:01
Data point term sent to Coder	System	20 Nov 2020 20:46:16
User entered 'OXYCODONE/ACETAMINOPHEN'	Shanice Bennett (b) (4)	20 Nov 2020 20:45:15

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'No (N)'	Shanice Bennett (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 01:30:51
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'ae already recorded' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:22:54
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:08:00
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User closed query 'Per CDM, DM CLR re-query: Thank you for the update. Please also ensure to update the Med His and AE entries to reflect the type of arthritis. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:54:09
Query 'Per CDM, DM CLR re-query: Thank you for the update. Please also ensure to update the Med His and AE entries to reflect the type of arthritis. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 13:38:18
User closed query 'Per DM CLR: Please review and update the indication to reflect the type of ARTHRITIS (e.g. Osteoarthritis or Rheumatoid).Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:37:00

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:28

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM, DM CLR re-query: Thank you for the update. Please also ensure to update the Med His and AE entries to reflect the type of arthritis. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:36:58
Query 'Per DM CLR: Please review and update the indication to reflect the type of ARTHRITIS (e.g. Osteoarthritis or Rheumatoid).Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 19:14:03
User entered 'WORSENING RIGHT KNEE otsteoARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jan 2021 19:13:58
User opened query 'Per DM CLR: Please review and update the indication to reflect the type of ARTHRITIS (e.g. Osteoarthritis or Rheumatoid).Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 08:44:47
User entered 'WORSENING RIGHT KNEE ARTHRITIS'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:15



**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered '10/325'	Shanice Bennett (b) (4)	20 Nov 2020 20:45:15

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'mg (mg)'	Shanice Bennett (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'as needed (PRN)'	Shanice Bennett (b) (4)	20 Nov 2020 20:45:15

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:52:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 20:45:15

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	20 Nov 2020 20:45:15

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:52:28**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 20:45:15

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered '09 Nov 2020'	Shanice Bennett (b) (4)	20 Nov 2020 20:45:15



**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered '0'	Shanice Bennett (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 00:51:53
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 14:29:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 14:29:08
User opened query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 05:46:53
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:52:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 14:29:08
User entered empty.	Shanice Bennett (b) (4)	20 Nov 2020 20:45:15

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:02:39
User entered 'No (N)'	Shanice Bennett (b) (4)	20 Nov 2020 20:45:15

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User entered empty.	System	20 Nov 2020 20:45:15

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User entered empty.	System	20 Nov 2020 20:45:15

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:52:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 00:41:28
Data hard unlocked.	(b) (4), (b) (6)	25 Apr 2021 11:48:47
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:48:40
User entered empty.	System	20 Nov 2020 20:45:15

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 14:21:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 14:21:57
Data point term sent to Coder	System	22 Apr 2021 14:21:40
User entered 'ambien'	(b) (4), (b) (6)	22 Apr 2021 14:21:02



US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:52:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:02

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'insomnia'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:02

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '10'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:02

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:02

US3022291

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:02

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:02

US3022291

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:02

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:02



US3022291

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:02

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:02

US3022291

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:02

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:02

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:02

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:21:02

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 14:21:02

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 14:21:02



**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:52:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 14:21:02

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Apr 2021 14:26:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 14:26:57
Data point term sent to Coder	System	22 Apr 2021 14:25:44
User entered 'fluoxetine'	(b) (4), (b) (6)	22 Apr 2021 14:25:27

US3022291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:52:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:25:27

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'depression'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:25:27

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '40'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:25:27

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:25:27

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:25:27

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:25:27



US3022291

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:25:27

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:25:27

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:25:27

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:25:27

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:25:27

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:25:27

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:25:27

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:21:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 14:25:27



**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Apr 2021 14:25:27

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 14:25:27

**US3022291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:52:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 14:25:27

US3022291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:52:28

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:59
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 20:45:24
User entered 'No (N)'	Shanice Bennett (b) (4)	16 Sep 2020 19:30:00

**US3022291**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 14:52:28**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '09 Nov 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:44

US3022291

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'RIGHT KNEE REPLACEMENT'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:44

**US3022291**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'Adverse Event (AE)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:44

US3022291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:52:28

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 20:45:44



**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'USA-US051-2020-MRNA-1273-P301000013'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Yes (Y)'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Yes (Y)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42



US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Paul'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Bradley'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered '340 Eisenhower Dr.'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Savannah'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'GA'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered '31406'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'US'	(b) (4) System	24 Nov 2020 01:00:12

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '2'	(b) (4)	21 Jan 2021 22:09:28
User entered '1'	System	24 Nov 2020 01:00:12



**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'USA-US051-2020-MRNA-1273-P301000013'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Yes (Y)'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Yes (Y)'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42



US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Paul'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Bradley'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered '340 Eisenhower Dr.'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Savannah'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'GA'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered '31406'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'US'	(b) (4) System	24 Nov 2020 01:00:12

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '2'	(b) (4)	21 Jan 2021 22:09:28
User entered '1'	System	24 Nov 2020 01:00:12



**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:52:28**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '24/Nov/2020 01:00'	(b) (4) System	24 Nov 2020 01:00:12

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:52:28

**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)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 01:00:12

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'USA-US051-2020-MRNA-1273-P301000013'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Yes (Y)'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:28

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Yes (Y)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42



US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'No (N)'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Paul'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Bradley'	System	24 Nov 2020 00:59:42

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:28

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered '340 Eisenhower Dr.'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'Savannah'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered 'GA'	System	24 Nov 2020 00:59:42

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 01:00:06
User entered '31406'	System	24 Nov 2020 00:59:42



**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:52:28**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'US'	(b) (4) System	24 Nov 2020 01:00:12

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 14:52:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '2'	(b) (4)	21 Jan 2021 22:09:28
User entered '1'	System	24 Nov 2020 01:00:12

**US3022291**

**Folder: SAE USA-US051-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:52:28**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered '21/Jan/2021 17:09'	(b) (4) System	21 Jan 2021 22:09:28

US3022291

Folder: SAE USA-US051-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:52:28

**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)	08 Apr 2021 16:49:25
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:36:25
User entered 'I'	(b) (4), (b) (6)	21 Jan 2021 22:09:28