

US3222311 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:07:28

All time stamps listed in this document are displayed in GMT

US3222311

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 14:46:43

Generated On: 09 Jun 2021 16:07:28

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[Participant ID](#)

US3222311

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

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US3222311

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	68
Age Units	YEARS
Age (Derived)	68
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

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) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

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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) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

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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) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Condition	DEMENTIA
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Condition	RIGHT HIP REPLACEMENT
Start date (dd MMM yyyy)	12 FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	12 FEB 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	FEB 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Condition	HIP SURGERY
Start date (dd MMM yyyy)	02 OCT 2018
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)	02 OCT 2018
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2018
Start Year (derived)	2018
Stop Month and Year (derived)	OCT 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Condition	CVA
Start date (dd MMM yyyy)	01 APR 2006
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)	APR 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Condition	TIA
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: Medical History (11)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Condition	URINARY INCONTINENCE
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Condition	MUSCLE SPASMS
Start date (dd MMM yyyy)	01 APR 2006
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)	APR 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Condition	GASTRODUODENAL ULCER
Start date (dd MMM yyyy)	01 APR 2006
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)	APR 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	24 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:16 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 13:16
Height ( <i>xxx.x</i> )	172.1 cm
Weight ( <i>xxx.x</i> )	74.8 kg
BMI ( <i>xxx.x</i> )	25.25456 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

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: Screening

Form: Childbearing Potential

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

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*) UN UNK 2007

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

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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** RETIRED

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

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) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

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

What was the participant's randomization number? 188027

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) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

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) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

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)	13:20 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 13:20
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	15:35 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 15:35
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

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) 15:01 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 15:01

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) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

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

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

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	14:34	24 AUG 2020 14:34
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

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 16:07:28

**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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 15:29

PC Open Date & Time

24 AUG 2020 15:21

PC Close Date & Time

24 AUG 2020 17:51

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**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 98.2 °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	24 AUG 2020 22:09
PC Open Date & Time	24 AUG 2020 18:46
PC Close Date & Time	25 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**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

98.4 °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

25 AUG 2020 19:17

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59



US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**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

98.4 °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

26 AUG 2020 21:55

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

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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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 21:37

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**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

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

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 23:23

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**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

24 AUG 2020 15:30

PC Open Date & Time

24 AUG 2020 15:21

PC Close Date & Time

24 AUG 2020 17:51

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**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

24 AUG 2020 22:11

PC Open Date & Time

24 AUG 2020 18:46

PC Close Date & Time

25 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**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

25 AUG 2020 19:17

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59



US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**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

26 AUG 2020 21:56

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**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 ☐

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

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**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

28 AUG 2020 21:38

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**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 ☐

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

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**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 23:23

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**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 ☐

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 15:31
PC Open Date & Time	24 AUG 2020 15:21
PC Close Date & Time	24 AUG 2020 17:51

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**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 ☐



US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 22:12
PC Open Date & Time	24 AUG 2020 18:46
PC Close Date & Time	25 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**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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US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 19:18
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 21:57
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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 ☐

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

Yes ☐

PC Time stamp

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

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)



US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 21:38
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

Yes ☐

PC Time stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 23:24
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3222311

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

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*

US3222311

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

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*



US3222311

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

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*

US3222311

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

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 SEP 2020
Time of assessment (00:00-23:59)	12:08 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 12:08
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

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)	23 SEP 2020
Time of assessment (00:00-23:59)	12:34 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 12:34
Temperature (xxx.x)	36.7 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3222311

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3222311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 12:51 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 12:51

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



US3222311

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 SEP 2020
Collection time (00:00-23:59)	12:18 (24 HR)
Collection date and time (derived)	23 SEP 2020 12:18

US3222311

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:15	23 SEP 2020 12:15
Nasopharyngeal Swab 2	No		

US3222311

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**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

98.0 °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

23 SEP 2020 13:20

PC Open Date & Time

23 SEP 2020 13:11

PC Close Date & Time

23 SEP 2020 15:41

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**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

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	23 SEP 2020 22:22
PC Open Date & Time	23 SEP 2020 16:36
PC Close Date & Time	24 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**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

98.2 °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

24 SEP 2020 22:32

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 21:51

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 23:05

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59



US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**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

99.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 20:01

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**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

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

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	29 SEP 2020 16:59
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

DAY 9

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**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

23 SEP 2020 13:21

PC Open Date & Time

23 SEP 2020 13:11

PC Close Date & Time

23 SEP 2020 15:41

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**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

23 SEP 2020 22:23

PC Open Date & Time

23 SEP 2020 16:36

PC Close Date & Time

24 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**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

24 SEP 2020 22:33

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**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

25 SEP 2020 21:51

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**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

26 SEP 2020 23:05

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**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

27 SEP 2020 20:02

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**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 ☐

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

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**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

29 SEP 2020 17:00

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**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 ☐

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 13:21
PC Open Date & Time	23 SEP 2020 13:11
PC Close Date & Time	23 SEP 2020 15:41

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**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 ☐



US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 22:23
PC Open Date & Time	23 SEP 2020 16:36
PC Close Date & Time	24 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**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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US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 22:34
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

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 ☒

PRODUCTION RELEASE (v12.003

107 of 2629

EAB) (1725)

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 21:52
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**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)

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 23:06
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**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 ☒

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EAB) (1725)

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US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 20:02
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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 ☐

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

Yes ☐

PC Time stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

	Yes <input type="radio"/>
PC Time stamp	29 SEP 2020 17:01
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3222311

Folder: Diary Dose 2 (1)

Form: Chills\_Day(8)

Generated On: 09 Jun 2021 16:07:28

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of **CHILLS** you  
are experiencing

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

---

PC Open Date & Time

30 SEP 2020 12:00

---

PC Close Date & Time

01 OCT 2020 11:59

---

PC Time stamp

---

US3222311

Folder: Diary Dose 2 (1)

Form: Chills\_Day(9)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

PC Time stamp

US3222311

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:07:28

TIMEPOINT	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59



US3222311

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:07:28

TIMEPOINT	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3222311

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222311

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222311

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222311

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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



US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3222311

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3222311

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	20 OCT 2020
Collection time ( <i>00:00-23:59</i> )	12:40 (24 HR)
Collection date and time (derived)	20 OCT 2020 12:40

US3222311

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:47:31

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59



US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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

09 NOV 2020 14:08:18

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2020 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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	29 NOV 2020 20:21:04
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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06 DEC 2020 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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09 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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13 DEC 2020 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	20 DEC 2020 13:03:59
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2020 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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>	30 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JAN 2021 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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](#)

13 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

<b>TIMEPOINT</b>	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	24 JAN 2021 13:28:00
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JAN 2021 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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>	03 FEB 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 FEB 2021 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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](#)

10 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☒

Yes ☐

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

17 FEB 2021 14:11:36

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 FEB 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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](#)

03 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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10 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAR 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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

24 MAR 2021 10:44:03

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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](#)

31 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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>	21 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 APR 2021 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAY 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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](#)

12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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>	02 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JUN 2021 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUN 2021 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐ Yes ☐

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

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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>	07 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2021 23:59



US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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>	04 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 AUG 2021 23:59



US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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>	11 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2021 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐  
Yes ☐

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

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐ Yes ☐

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

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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>	20 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2021 23:59
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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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



US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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](#)

03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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°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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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

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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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



US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐  
Yes ☐

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

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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](#)

12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JAN 2022 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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°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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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

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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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09 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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°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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐ Yes ☐

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

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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



US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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>	20 APR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 APR 2022 23:59
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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐  
Yes ☐

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

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐ Yes ☐

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

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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](#)

25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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°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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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](#)

29 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐  
Yes ☐

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

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 JUL 2022 23:59



US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUL 2022 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐  
Yes ☐

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

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐  
Yes ☐

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

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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](#)

03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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>	24 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59
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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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>	07 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 SEP 2022 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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 <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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 SEP 2022 23:59

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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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21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 SEP 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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="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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59



US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 OCT 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**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 ☐

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

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US3222311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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"/>

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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"/>
---	--

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



US3222311

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:07:28

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		24 MAR 2021 10:44:47

US3222311

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222311

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222311

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222311

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:13:05

Generated On: 09 Jun 2021 16:07:28

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*



US3222311

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

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

Visit date (dd MMM yyyy)	30 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3222311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3222311

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3222311

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	12:15 (24 HR)
Collection date and time (derived)	30 MAR 2021 12:15

US3222311

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222311

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3222311**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:07:28**

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*

**US3222311**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222311

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:07:28

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

**US3222311**

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

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

**Generated On: 09 Jun 2021 16:07:28**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3222311

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

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

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

Visit date (dd MMM yyyy)	28 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3222311

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Date of updated informed consent ( <i>dd MMM yyyy</i> )	28 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	28 JAN 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

US3222311

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Height	172.7 cm
Weight	74.8 kg
BMI (xxx.x)	25.07939

US3222311

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Height	172.7 cm
Weight	74.8 kg
BMI (xxx.x)	25.07939
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 JAN 2021
Time of assessment (00:00-23:59)	12:24 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 12:24
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG



US3222311

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 14:46:44

Generated On: 09 Jun 2021 16:07:28

Height	172.7 cm
Weight	74.8 kg
BMI (xxx.x)	25.07939
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)	28 JAN 2021
Time of assessment (00:00-23:59)	13:35 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 13:35
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3222311

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

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 14:46:43

Generated On: 09 Jun 2021 16:07:28

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

28 JAN 2021

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

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US3222311

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

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 14:46:43

Generated On: 09 Jun 2021 16:07:28

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) 28 JAN 2021

What was the treatment time? (00:00-23:59) 13:04 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 13:04

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

US3222311

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 14:46:43

Generated On: 09 Jun 2021 16:07:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00-23:59)	12:45 (24 HR)
Collection date and time (derived)	28 JAN 2021 12:45

US3222311

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 20 Feb 2021 14:46:43

Generated On: 09 Jun 2021 16:07:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	28 JAN 2021
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Collection time (00:00 - 23:59)	12:47
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Collection Date and Time (derived)	28 JAN 2021 12:47
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US3222311

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

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 14:46:43

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222311

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

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



US3222311

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

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)	25 FEB 2021
Time of assessment (00:00-23:59)	12:08 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 12:08
Temperature (xxx.x)	37 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

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)	25 FEB 2021
Time of assessment (00:00-23:59)	13:39 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 13:39
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	41 mmHg
Diastolic Blood Pressure units	MMHG

US3222311

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3222311

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

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) 25 FEB 2021

What was the treatment time? (00:00-23:59) 13:09 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 13:09

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

US3222311

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222311

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 21:18:18

Generated On: 09 Jun 2021 16:07:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222311

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:18:18

Generated On: 09 Jun 2021 16:07:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3222311

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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	OLD57

US3222311

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	30 MAR 2021
Collection time ( <i>00:00-23:59</i> )	12:15 (24 HR)
Collection date and time (derived)	30 MAR 2021 12:15

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Feb 2021 14:46:43

Generated On: 09 Jun 2021 16:07:28

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3222311

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

AEID	USA-US104-2020-MRNA-1273-P30 1000012
Adverse event	URINARY TRACT INFECTION
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)	28 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 SEP 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)	28 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	30 SEP 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) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

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	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3222311

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

---

FOUND OUT TODAY @ 11:21 AM  
THAT THE SUBJECT HAD  
FALLEN AND STARTED TO  
EXPERIENCE TINGLING TO THE  
RIGHT SIDE AND WAS  
ADMITTED TO THE HOSPITAL.  
RULED OUT STROKE AND  
CONFIRMED UTI.  
SHE HAS A HISTORY OF CVA  
WITH RESIDUAL DEFICITS.

---

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

---



US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

AEID	
Adverse event	FALL
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)	30 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

4 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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	SUBJECT WAS DX WITH UTI ON 12/4 AND IS PROCEEDING WITH A 10 DAY COURSE OF LEVAQUIN 500 MG QD.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

AEID	
Adverse event	KNEE PAIN
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:08:12

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Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒  
Related ☐  
Not Applicable ☐

Relationship to Study Procedure Not Related ☒  
Related ☐  
Not Applicable ☐

Action taken with investigational product None ☒  
Dose Delayed ☐  
Investigational Product ☐  
Withdrawn ☐  
Not Applicable ☐

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal ☐  
Not Recovered/Not Resolved ☐  
Recovered/Resolved ☒  
Recovered/Resolved with Sequelae ☐  
Recovering/Resolving ☐  
Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative THIS AE IS SECONDARY TO FALL IN SEP 2020. SUBJECT STATED SHE HAS ARTHRITIS AND THAT IS WHAT THE PAIN IS FROM.

Serious Adverse Event Derived (CSA Programming Field Only) 0

Medically Attended AE Derived (CSA Programming Field Only) 0

Admitted to ICU Derived (CSA Programming Field Only)

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

AEID

Adverse event

MOHS SURGERY

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	REMOVED BASAL CELL CARCINOMA FROM LEFT CHEAK.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 20 Feb 2021 14:46:43

Generated On: 09 Jun 2021 16:07:28

---

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

Yes ☒

No ☐

---

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

---

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)		01 JAN 2006
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication BACLOFEN

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE SPASMS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)		01 APR 2006
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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication DONEPEZIL

Prophylaxis Yes ☐  
No ☒

Indication DEMENTIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication DULOXETINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)	01 JAN 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication DIVALPROEX

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)	01 JAN 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)	01 JAN 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOPARATHYROID

Dose per administration 0.88

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)	01 JAN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication NAMENDA

Prophylaxis Yes ☐  
No ☒

Indication DEMENTIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)	01 JAN 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTRODUODENAL ULCER

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)	01 APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)		01 JAN 2006
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication DETROL LA

Prophylaxis Yes ☐  
No ☒

Indication URINARY INCONTINENCE

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)	01 JAN 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication CEFDINIR

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		5 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication \_\_\_\_\_

Prophylaxis Yes ☐  
No ☐

Indication \_\_\_\_\_

Dose per administration \_\_\_\_\_

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

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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) _____		
Start date completely unknown _____		
Ongoing?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication POSTOPERATIVE HIP PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)		29 SEP 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 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication BACTRIM - TRIMETHOPRIM /  
SULFAMETHOXAZOLE

Prophylaxis Yes ☐  
No ☒

Indication UTI

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)	5 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication INFLUENZA

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS SEASONAL  
INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication LEVAQUIN

Prophylaxis Yes ☐  
No ☒

Indication UTI

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)	05 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication KNEE PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication CEPHALEXIN

Prophylaxis Yes ☐  
No ☒

Indication PRE-OP MOHS SURGERY BASAL  
CELL CARCINOMA EXCISED  
FROM CHEAK.

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify Q6-12HS X 4

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)		01 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐  
No ☒

Indication MOHS SURGERY FOR BASAL  
CELL REMOVED

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

QD X 5 DAYS

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 14:08:12

Generated On: 09 Jun 2021 16:07:28

	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)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 14:08:13

Generated On: 09 Jun 2021 16:07:28

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
02 FEB 2021	MOHS SURGERY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:07:28

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:07:28

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 ☐

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:13:05

Generated On: 09 Jun 2021 16:07:28

SAEID	USA-US104-2020-MRNA-1273-P301000012
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5



US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:13:05

Generated On: 09 Jun 2021 16:07:28

SAEID	USA-US104-2020-MRNA-1273-P301000012
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/OCT/2020 14:57
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

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:13:05

Generated On: 09 Jun 2021 16:07:28

SAEID	USA-US104-2020-MRNA-1273-P301000012
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/NOV/2020 19:37
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

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 22:13:05

Generated On: 09 Jun 2021 16:07:28

SAEID	USA-US104-2020-MRNA-1273-P301000012
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/NOV/2020 12:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 22:13:05

Generated On: 09 Jun 2021 16:07:28

SAEID	USA-US104-2020-MRNA-1273-P301000012
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	03/DEC/2020 10:03
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

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 22:13:05

Generated On: 09 Jun 2021 16:07:28

SAEID	USA-US104-2020-MRNA-1273-P301000012
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/APR/2021 11:19
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

US3222311 (Prod: Accel Research Site - Avail - ERN-PPDS)

**US3222311**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:07:28**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'US3222311'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:14:44

US3222311

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	24 Aug 2020 19:12:20



US3222311

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:14:45

US3222311

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[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 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	24 Aug 2020 19:12:20

**US3222311**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:07:28**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'SCRN'	System	24 Aug 2020 19:12:20

US3222311

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:28

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered (b) (6) 1952'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:14:46

US3222311

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:28

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '68'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:06:31

**US3222311**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:07:28**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'YEARS'	System	25 Aug 2020 14:06:31

**US3222311**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:07:28**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '68'	System	24 Aug 2020 19:12:30

US3222311

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:28

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Female (F)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:06:31



US3222311

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:28

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:06:31

**US3222311**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:07:28**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'I'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:06:31

US3222311

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:28

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:06:31

US3222311

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:28

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:06:31

**US3222311**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:07:28**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:06:31

US3222311

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:28

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:06:31

US3222311

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:06:31

US3222311

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:28

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:06:31



**US3222311**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:07:28**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:06:31

US3222311

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:07:28

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:06:31

US3222311

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:07:28

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:02:46
User entered '24 Aug 2020'	Jennifer Dittman (b) (4) (b) (4)	24 Aug 2020 19:12:30

**US3222311**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:07:28**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Aug 2020'	System	24 Aug 2020 19:12:30

**US3222311**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:07:28**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2020'	System	24 Aug 2020 19:12:30

**US3222311**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:07:28**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:02:46
User entered 'Amendment 2 (2)'	Jennifer Dittman (b) (4) (b) (4)	24 Aug 2020 19:12:30

US3222311

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:07:28

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:02:46
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	24 Aug 2020 19:12:30

**US3222311**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:07:28**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:02:46
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	24 Aug 2020 19:12:30



US3222311

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:07:28

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:02:46
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	24 Aug 2020 19:12:30

**US3222311**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:07:28**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:02:46
User entered 'No (N)'	Jennifer Dittman (b) (4) (b) (4)	24 Aug 2020 19:12:30

**US3222311**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:07:28**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:02:46
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:14:45

**US3222311**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:07:28**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'I'	System	24 Aug 2020 19:12:36

US3222311

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	24 Aug 2020 19:12:36

US3222311

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:07:28

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:08:04

US3222311

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:07:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 14:17:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 14:17:29
Data point term sent to Coder	System	25 Aug 2020 14:16:51
User entered 'Postmenopausal'	Amber Vasquez (b) (4)	25 Aug 2020 14:16:29

**US3222311**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'un UNK 2007'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:16:29



US3222311

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:16:29

**US3222311**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:16:29

**US3222311**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:07:28**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:16:29

**US3222311**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:16:29

**US3222311**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Jan 2007'	System	25 Aug 2020 14:16:29

**US3222311**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2007'	System	25 Aug 2020 14:16:29

**US3222311**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	25 Aug 2020 14:16:29

**US3222311**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	25 Aug 2020 14:16:29



US3222311

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 17:02:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 17:02:13
Data point term sent to Coder	System	31 Oct 2020 17:01:32
User entered 'ANXIETY'	douglas winter (b) (4)	31 Oct 2020 17:01:04
	(b) (4)	

US3222311

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'UN UNK 2010'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:01:04

US3222311

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:01:04

**US3222311**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:01:04

US3222311

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:01:04

US3222311

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:07:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:01:04

**US3222311**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Jan 2010'	System	31 Oct 2020 17:01:04

**US3222311**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2010'	System	31 Oct 2020 17:01:04



**US3222311**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:01:04

**US3222311**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:01:04

US3222311

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User coded data point as SOC: Nervous system disorders, HLGT: Mental impairment disorders, HLT: Dementia (excl Alzheimer's type), PT: Dementia, LLT: Dementia - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 17:02:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 17:02:13
Data point term sent to Coder	System	31 Oct 2020 17:01:32
User entered 'DEMENTIA'	douglas winter (b) (4)	31 Oct 2020 17:01:22
	(b) (4)	

US3222311

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'UN UNK 2013'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:01:22

US3222311

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:01:22

**US3222311**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:01:22

US3222311

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:01:22

US3222311

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:07:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:01:22



**US3222311**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Jan 2013'	System	31 Oct 2020 17:01:22

**US3222311**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2013'	System	31 Oct 2020 17:01:22

**US3222311**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:01:22

**US3222311**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:01:22

US3222311

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User closed query 'Per CDM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 16:37:21
Query 'Per CDM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'MED HX ADDED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:18:15
User opened query 'Per CDM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 06:02:51
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 17:04:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 17:04:14
Data point term sent to Coder	System	31 Oct 2020 17:03:33
User entered 'RIGHT HIP REPLACEMENT'	douglas winter (b) (4) (b) (4)	31 Oct 2020 17:02:57

US3222311

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '12 Feb 2020'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:02:57

US3222311

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:02:57

**US3222311**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:02:57



US3222311

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '12 Feb 2020'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:02:57

US3222311

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:07:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:02:57

**US3222311**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Feb 2020'	System	31 Oct 2020 17:02:57

**US3222311**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2020'	System	31 Oct 2020 17:02:57

**US3222311**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Feb 2020'	System	31 Oct 2020 17:02:57

**US3222311**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2020'	System	31 Oct 2020 17:02:57

US3222311

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:07:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User closed query 'Per CDM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 16:37:43
Query 'Per CDM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'MED HX ADDED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:18:51
User opened query 'Per CDM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 06:03:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip surgery, LLT: Hip surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 17:05:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Oct 2020 17:05:15
Data point term sent to Coder	System	31 Oct 2020 17:04:33
User entered 'HIP SURGERY'	douglas winter (b) (4) (b) (4)	31 Oct 2020 17:03:46

US3222311

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:07:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '02 Oct 2018'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:03:46



US3222311

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:03:46

**US3222311**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:07:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:03:46

US3222311

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:07:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '02 Oct 2018'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:03:46

**US3222311**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:03:46

**US3222311**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Oct 2018'	System	31 Oct 2020 17:03:46

**US3222311**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2018'	System	31 Oct 2020 17:03:46

**US3222311**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Oct 2018'	System	31 Oct 2020 17:03:46

**US3222311**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2018'	System	31 Oct 2020 17:03:46



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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 17:05:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 17:05:15
Data point term sent to Coder	System	31 Oct 2020 17:04:35
User entered 'HYPERCHOLESTEROLEMIA'	douglas winter (b) (4)	31 Oct 2020 17:04:10

US3222311

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'UN UNK 2000'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:10

US3222311

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:10

US3222311

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:10

US3222311

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:10

US3222311

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:07:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:10

**US3222311**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Jan 2000'	System	31 Oct 2020 17:04:10

**US3222311**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2000'	System	31 Oct 2020 17:04:10



**US3222311**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:04:10

**US3222311**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:04:10

US3222311

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:07:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 17:05:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 17:05:15
Data point term sent to Coder	System	31 Oct 2020 17:04:35
User entered 'HYPERTENSION'	douglas winter (b) (4)	31 Oct 2020 17:04:34

US3222311

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:07:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'UN UNK 2000'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:34

US3222311

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:34

**US3222311**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:07:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:34

US3222311

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:07:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:34

**US3222311**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:34



**US3222311**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Jan 2000'	System	31 Oct 2020 17:04:34

**US3222311**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2000'	System	31 Oct 2020 17:04:34

**US3222311**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:04:34

**US3222311**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:04:34

US3222311

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User closed query 'Per CDM 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 for no medical treatment.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 16:39:48
' (Site from DM).		
Query 'Per CDM 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 for no medical treatment.	Alicia Cevera (b) (4)	12 Feb 2021 12:10:13
' answered with 'CONFIRM LISTED ON CONMED PAGE' (Site from DM).	(b) (4)	
User opened query 'Per CDM 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 for no medical treatment.	(b) (4), (b) (6)	13 Jan 2021 06:03:40
' (Site from DM).		
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4)	31 Oct 2020 17:06:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	31 Oct 2020 17:06:15
User entered 'HYPOTHYROIDISM'	System	31 Oct 2020 17:05:36
	douglas winter (b) (4)	31 Oct 2020 17:04:58
	(b) (4)	

US3222311

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'UN UNK 2018'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:58

US3222311

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:28

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:58

US3222311

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:58



US3222311

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:58

US3222311

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:07:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:04:58

**US3222311**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Jan 2018'	System	31 Oct 2020 17:04:58

**US3222311**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2018'	System	31 Oct 2020 17:04:58

**US3222311**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:04:58

**US3222311**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:04:58

US3222311

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: CVA - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 17:07:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 17:07:16
Data point term sent to Coder	System	31 Oct 2020 17:06:38
User entered 'CVA'	douglas winter (b) (4)	31 Oct 2020 17:05:37

US3222311

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '01 Apr 2006'	(b) (4) douglas winter (b) (4)	31 Oct 2020 17:05:37
	(b) (4)	



US3222311

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:05:37

US3222311

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:05:37

US3222311

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:05:37

US3222311

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:05:37

US3222311

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:07:28

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Apr 2006'	System	31 Oct 2020 17:05:37

**US3222311**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2006'	System	31 Oct 2020 17:05:37

**US3222311**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:05:37

**US3222311**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:05:37



US3222311

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: TIA - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 17:07:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 17:07:16
Data point term sent to Coder	System	31 Oct 2020 17:06:38
User entered 'TIA'	douglas winter (b) (4)	31 Oct 2020 17:05:58

US3222311

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'UN UNK 2015'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:05:58

US3222311

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:05:58

US3222311

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:05:58

US3222311

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) douglas winter (b) (4)	31 Oct 2020 17:05:58

US3222311

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:07:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:05:58

**US3222311**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Jan 2015'	System	31 Oct 2020 17:05:58

**US3222311**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2015'	System	31 Oct 2020 17:05:58



**US3222311**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:05:58

**US3222311**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:05:58

US3222311

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:07:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 17:08:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 17:08:16
Data point term sent to Coder	System	31 Oct 2020 17:07:39
User entered 'URINARY INCONTINENCE'	douglas winter (b) (4)	31 Oct 2020 17:06:53

US3222311

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:07:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'UN UNK 2006'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:06:53

**US3222311**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:07:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:06:53

**US3222311**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:07:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:06:53

US3222311

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:07:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) douglas winter (b) (4)	31 Oct 2020 17:06:53

**US3222311**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:06:53



**US3222311**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Jan 2006'	System	31 Oct 2020 17:06:53

**US3222311**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2006'	System	31 Oct 2020 17:06:53

**US3222311**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:06:53

**US3222311**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	31 Oct 2020 17:06:53

US3222311

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:07:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 17:09:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 17:09:50
Data point term sent to Coder	System	17 Dec 2020 17:08:55
User entered 'MUSCLE SPASMS'	Albert Garcia (b) (4)	17 Dec 2020 17:08:49

US3222311

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:07:28

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '01 Apr 2006'	Albert Garcia (b) (4)	17 Dec 2020 17:08:49

US3222311

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	Albert Garcia (b) (4)	17 Dec 2020 17:08:49

**US3222311**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:07:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	Albert Garcia (b) (4)	17 Dec 2020 17:08:49



**US3222311**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:07:28**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	Albert Garcia (b) (4)	17 Dec 2020 17:08:49

US3222311

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:07:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	Albert Garcia (b) (4)	17 Dec 2020 17:08:49

**US3222311**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Apr 2006'	System	17 Dec 2020 17:08:49

**US3222311**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2006'	System	17 Dec 2020 17:08:49

**US3222311**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	17 Dec 2020 17:08:49

**US3222311**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	17 Dec 2020 17:08:49

US3222311

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:07:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 12:14:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 12:14:45
Data point term sent to Coder	System	12 Feb 2021 12:13:45
User entered 'OSTEOARTHRITIS BILATERAL HIPS'	Alicia Cevera (b) (4)	12 Feb 2021 12:12:54

**US3222311**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:07:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Alicia Cevera (b) (4)	12 Feb 2021 12:12:54



US3222311

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'I'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:12:54

**US3222311**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:07:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	12 Feb 2021 12:12:54

US3222311

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:07:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:12:54

US3222311

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:07:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:12:54

**US3222311**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	12 Feb 2021 12:12:54

**US3222311**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	12 Feb 2021 12:12:54

**US3222311**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	12 Feb 2021 12:12:54

**US3222311**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	12 Feb 2021 12:12:54



US3222311

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:07:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 12:48:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 12:48:45
Data point term sent to Coder	System	12 Feb 2021 12:47:50
User entered 'osteoarthritis bilateral knees'	Alicia Cevera (b) (4)	12 Feb 2021 12:47:04

**US3222311**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:07:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:47:04

US3222311

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'I'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:47:04

**US3222311**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:07:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Alicia Cevera (b) (4)	12 Feb 2021 12:47:04

**US3222311**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:07:28**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:47:04

US3222311

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:07:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:47:04

**US3222311**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	12 Feb 2021 12:47:04

**US3222311**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	12 Feb 2021 12:47:04



**US3222311**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	12 Feb 2021 12:47:04

**US3222311**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	12 Feb 2021 12:47:04

US3222311

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:07:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Duodenal ulcers and perforation, PT: Gastroduodenal ulcer, LLT: Gastroduodenal ulcer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	08 Apr 2021 17:59:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 17:59:51
Data point term sent to Coder	System	08 Apr 2021 17:59:00
User entered 'gastroduodenal ulcer'	(b) (4), (b) (6)	08 Apr 2021 17:58:49

**US3222311**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:07:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '01 Apr 2006'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:58:49

US3222311

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:58:49

**US3222311**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:07:28**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:58:49

US3222311

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:07:28

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:58:49

**US3222311**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:58:49



**US3222311**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'Apr 2006'	System	08 Apr 2021 17:58:49

**US3222311**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:07:28**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '2006'	System	08 Apr 2021 17:58:49

**US3222311**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	08 Apr 2021 17:58:49

**US3222311**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:07:28**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered empty.	System	08 Apr 2021 17:58:49

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:17:50

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '24 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:17:50

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '13:16'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:17:50

**US3222311**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '24 Aug 2020 13:16'	System	25 Aug 2020 14:17:50



US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '172.1' cm	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:17:50
DataPoint set to visible.	(b) (4) System	24 Aug 2020 19:12:36

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '74.8' kg	(b) (4)	
	Amber Vasquez (b) (4)	25 Aug 2020 14:17:50
DataPoint set to visible.	(b) (4)	
	System	24 Aug 2020 19:12:36

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
Amendment Manager: User entered '25.25456'	System	17 Sep 2020 00:21:39
User entered '25.3'	System	25 Aug 2020 14:17:50
DataPoint set to visible.	System	24 Aug 2020 19:12:36

**US3222311**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'kg/m2'	System	25 Aug 2020 14:17:50
DataPoint set to visible.	System	24 Aug 2020 19:12:36

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 20:08:43
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:45:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:45:04
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 16:21:20
User entered '37.2' C	Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 14:17:50

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	20 Sep 2020 21:45:04
User entered 'Oral (Oral)'	Amber Vasquez (b) (4)	25 Aug 2020 14:17:50

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:17:50

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:45:04
User entered '66'	Albert Garcia (b) (4)	25 Aug 2020 14:17:50
	(b) (4)	



**US3222311**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'bpm'	System	25 Aug 2020 14:17:50

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:45:04
User entered '16'	Albert Garcia (b) (4)	25 Aug 2020 14:17:50
	(b) (4)	

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'breaths/min'	System	25 Aug 2020 14:17:50

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:45:04
User entered '122'	Albert Garcia (b) (4)	25 Aug 2020 14:17:50
	(b) (4)	

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'mmHg'	System	25 Aug 2020 14:17:50

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Sep 2020 21:45:04
User entered '68'	Albert Garcia (b) (4)	25 Aug 2020 14:17:50
	(b) (4)	

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'mmHg'	System	25 Aug 2020 14:17:50

US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35



US3222311

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35

US3222311

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:18:46

US3222311

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '24 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:18:46

US3222311

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '24 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:09

US3222311

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:28

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:09

US3222311

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:28

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:09

US3222311

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:28

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:09

US3222311

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:28

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:09



US3222311

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:28

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:09

US3222311

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:28

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'un UNK 2007'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:09

US3222311

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:07:28

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:09

US3222311

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:28

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

Form: Risk of Exposure

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**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

Form: Risk of Exposure

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**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)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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**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)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

Form: Risk of Exposure

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Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:50



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[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)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

Form: Risk of Exposure

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**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)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

Form: Risk of Exposure

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

Form: Risk of Exposure

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[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)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

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**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

Form: Risk of Exposure

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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Retired'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:50



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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'I'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:28

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:28

**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)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:28

[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)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:28

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)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '0'	Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:28

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '0'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:50

US3222311

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:07:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:19:50



US3222311

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	24 Aug 2020 19:13:00

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '24 Aug 2020'	Jennifer Dittman (b) (4)	24 Aug 2020 19:13:00

US3222311

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	24 Aug 2020 19:13:00

**US3222311**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:07:28**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'VISIT1'	System	24 Aug 2020 19:13:00

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:34:48

US3222311

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:28

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '188027'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:34:48

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:28

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:34:48

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:28

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)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User closed query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:41:18
Query ' PER CDM: Please complete this section of the form' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:44:31
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	20 Sep 2020 21:44:27
User opened query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 19:39:01



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:28

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)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	Albert Garcia (b) (4)	20 Sep 2020 21:44:27

US3222311

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:28

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	Albert Garcia (b) (4)	20 Sep 2020 21:44:27

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:28

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	Albert Garcia (b) (4)	20 Sep 2020 21:44:27

US3222311

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:28

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	Albert Garcia (b) (4)	20 Sep 2020 21:44:27

US3222311

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:07:28

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	Albert Garcia (b) (4)	20 Sep 2020 21:44:27
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:40:17
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:42:42

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 11:38:32
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	06 Sep 2020 17:42:13
User entered '172.7' cm	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 11:38:32
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	06 Sep 2020 17:42:13
User entered '74.8' kg	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 11:38:32
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	06 Sep 2020 17:42:13
User entered '172.7' cm	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 11:38:32
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	06 Sep 2020 17:42:13
User entered '74.8' kg	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 14:23:41

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '24 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '13:20'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered '24 Aug 2020 13:20'	System	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '37.2' C	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Oral (Oral)'	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '66'	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'bpm'	System	25 Aug 2020 14:23:41

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '16'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'breaths/min'	System	25 Aug 2020 14:23:41

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '122'	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'mmHg'	System	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '67'	(b) (4) Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 14:23:41



US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'mmHg'	System	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 11:38:32
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	06 Sep 2020 17:42:13
User entered '172.7' cm	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 11:38:32
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	06 Sep 2020 17:42:13
User entered '74.8' kg	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '24 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '15:35'	(b) (4) Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered '24 Aug 2020 15:35'	System	25 Aug 2020 14:23:41



US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '37.1' C	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Oral (Oral)'	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	29 Sep 2020 13:45:02
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	29 Sep 2020 13:45:02
User entered '67' reason for change: Data Entry Error	Albert Garcia (b) (4)	29 Sep 2020 13:45:02
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	25 Aug 2020 14:23:41
User entered empty.	System	25 Aug 2020 14:23:41
	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41
	(b) (4)	

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'bpm'	System	29 Sep 2020 13:45:02
User entered empty.	System	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '16'	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'breaths/min'	System	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '116'	Amber Vasquez (b) (4)	25 Aug 2020 14:23:41



US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'mmHg'	System	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '76'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'mmHg'	System	25 Aug 2020 14:23:41

US3222311

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:07:40
User closed query 'Please removed data and mark as not done, this data is captured in the screening CRF.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 14:07:38
Query 'Please removed data and mark as not done, this data is captured in the screening CRF.' answered with 'UPDATED' (Site from CRA).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:15:43
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:15:40
User opened query 'Please removed data and mark as not done, this data is captured in the screening CRF.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:52:08
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 14:24:07

US3222311

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:07:40
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:15:40
User entered '24 Aug 2020'	Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 14:24:07

US3222311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	24 Aug 2020 19:13:39

US3222311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	Jennifer Dittman (b) (4)	24 Aug 2020 19:13:39

US3222311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

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)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	Jennifer Dittman (b) (4)	24 Aug 2020 19:13:39



US3222311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 19:13:39

US3222311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '24 Aug 2020'	Jennifer Dittman (b) (4)	24 Aug 2020 19:13:39

US3222311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '15:01'	Jennifer Dittman (b) (4)	24 Aug 2020 19:13:39

US3222311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered '24 Aug 2020 15:01'	System	24 Aug 2020 19:13:39

US3222311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	24 Aug 2020 19:13:39

US3222311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'ONCE'	System	24 Aug 2020 19:13:39

US3222311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 19:13:39

US3222311

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	25 Aug 2020 14:24:40



US3222311

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '24 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:24:40

US3222311

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '14:24'	(b) (4) Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 14:24:40

US3222311

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered '24 Aug 2020 14:24'	System	25 Aug 2020 14:24:40

US3222311

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:07:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '24 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:24:58

US3222311

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:07:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 14:24:58

US3222311

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:07:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:24:58

US3222311

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:07:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '14:34'	Amber Vasquez (b) (4)	25 Aug 2020 14:24:58

**US3222311**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered '24 Aug 2020 14:34'	System	25 Aug 2020 14:24:58



US3222311

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:07:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Vasquez (b) (4) (b) (4)	25 Aug 2020 14:24:58

US3222311

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:07:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:24:58

US3222311

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:07:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	Amber Vasquez (b) (4)	25 Aug 2020 14:24:58

**US3222311**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered empty.	System	25 Aug 2020 14:24:58

US3222311

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	25 Aug 2020 14:25:09

**US3222311**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'I'	System	25 Aug 2020 14:25:09

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:29:33', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '62abbfa1-21e1-4022-bd62-a737347d59ed'	System	24 Aug 2020 19:29:52
User entered 'Yes (Y)'	System	24 Aug 2020 19:29:52



US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:29:39', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '62abbfa1-21e1-4022-bd62-a737347d59ed'	System	24 Aug 2020 19:29:52
User entered '98.8'	System	24 Aug 2020 19:29:52

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:29:46', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '62abbfa1-21e1-4022-bd62-a737347d59ed'	System	24 Aug 2020 19:29:52
User entered 'No (N)'	System	24 Aug 2020 19:29:52

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:29:49', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '62abbfa1-21e1-4022-bd62-a737347d59ed'	System	24 Aug 2020 19:29:52
User entered '24 Aug 2020 15:29'	System	24 Aug 2020 19:29:52

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Aug 2020 15:21'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Aug 2020 17:51'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:09:06', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8ddddd8e0-2a2b-42eb-a2ba-2fd9fc8babbb'	System	25 Aug 2020 02:09:48
User entered 'Yes (Y)'	System	25 Aug 2020 02:09:48

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:09:17', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8ddddd8e0-2a2b-42eb-a2ba-2fd9fc8babbb'	System	25 Aug 2020 02:09:48
User entered '98.2'	System	25 Aug 2020 02:09:48



US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:09:25', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8ddddd8e0-2a2b-42eb-a2ba-2fd9fc8babbb'	System	25 Aug 2020 02:09:48
User entered 'No (N)'	System	25 Aug 2020 02:09:48

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:09:47', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8ddddd8e0-2a2b-42eb-a2ba-2fd9fc8babbb'	System	25 Aug 2020 02:09:48
User entered '24 Aug 2020 22:09'	System	25 Aug 2020 02:09:48

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Aug 2020 18:46'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 2'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:14:11', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '1e155b42-6df8-4126-a981-1d8fa9e8a17e'	System	25 Aug 2020 23:17:05
User entered 'Yes (Y)'	System	25 Aug 2020 23:17:05

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:16:51', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '1e155b42-6df8-4126-a981-1d8fa9e8a17e'	System	25 Aug 2020 23:17:05
User entered '98.4'	System	25 Aug 2020 23:17:05

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:16:55', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '1e155b42-6df8-4126-a981-1d8fa9e8a17e'	System	25 Aug 2020 23:17:05
User entered 'No (N)'	System	25 Aug 2020 23:17:05



US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:17:00', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '1e155b42-6df8-4126-a981-1d8fa9e8a17e'	System	25 Aug 2020 23:17:05
User entered '25 Aug 2020 19:17'	System	25 Aug 2020 23:17:05

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 3'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:54:50', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '4396f5bb-d394-47b7-83ef-db0444362b12'	System	27 Aug 2020 01:55:09
User entered 'Yes (Y)'	System	27 Aug 2020 01:55:09

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:54:56', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '4396f5bb-d394-47b7-83ef-db0444362b12'	System	27 Aug 2020 01:55:09
User entered '98.4'	System	27 Aug 2020 01:55:09

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:55:02', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '4396f5bb-d394-47b7-83ef-db0444362b12'	System	27 Aug 2020 01:55:09
User entered 'No (N)'	System	27 Aug 2020 01:55:09

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:55:06', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '4396f5bb-d394-47b7-83ef-db0444362b12'	System	27 Aug 2020 01:55:09
User entered '26 Aug 2020 21:55'	System	27 Aug 2020 01:55:09



US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 4'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25



US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 5'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:36:56', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '368daeec-d4ff-4d40-bb29-96d86e41052b'	System	29 Aug 2020 01:37:18
User entered 'Yes (Y)'	System	29 Aug 2020 01:37:18

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:37:01', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '368daeec-d4ff-4d40-bb29-96d86e41052b'	System	29 Aug 2020 01:37:18
User entered '98.5'	System	29 Aug 2020 01:37:18

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:37:05', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '368daeec-d4ff-4d40-bb29-96d86e41052b'	System	29 Aug 2020 01:37:18
User entered 'No (N)'	System	29 Aug 2020 01:37:18

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:37:17', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '368daeec-d4ff-4d40-bb29-96d86e41052b'	System	29 Aug 2020 01:37:18
User entered '28 Aug 2020 21:37'	System	29 Aug 2020 01:37:18



US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 6'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25



US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 7'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:22:40', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '64925736-c2f2-494d-8634-111b7fede4c0'	System	31 Aug 2020 03:23:02
User entered 'Yes (Y)'	System	31 Aug 2020 03:23:02

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:22:53', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '64925736-c2f2-494d-8634-111b7fede4c0'	System	31 Aug 2020 03:23:02
User entered '98.7'	System	31 Aug 2020 03:23:02

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:22:57', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '64925736-c2f2-494d-8634-111b7fede4c0'	System	31 Aug 2020 03:23:02
User entered 'No (N)'	System	31 Aug 2020 03:23:02

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:23:00', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '64925736-c2f2-494d-8634-111b7fede4c0'	System	31 Aug 2020 03:23:02
User entered '30 Aug 2020 23:23'	System	31 Aug 2020 03:23:02



US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:29:58', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '9662b184-d40a-447f-b08a-7b1a1b864ddf'	System	24 Aug 2020 19:30:47
User entered 'None (1)'	System	24 Aug 2020 19:30:47

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:30:25', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '9662b184-d40a-447f-b08a-7b1a1b864ddf'	System	24 Aug 2020 19:30:47
User entered 'No (N)'	System	24 Aug 2020 19:30:47

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:30:31', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '9662b184-d40a-447f-b08a-7b1a1b864ddf'	System	24 Aug 2020 19:30:47
User entered 'No (N)'	System	24 Aug 2020 19:30:47

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:30:39', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '9662b184-d40a-447f-b08a-7b1a1b864ddf'	System	24 Aug 2020 19:30:47
User entered 'None (1)'	System	24 Aug 2020 19:30:47

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:30:42', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '9662b184-d40a-447f-b08a-7b1a1b864ddf'	System	24 Aug 2020 19:30:47
User entered '24 Aug 2020 15:30'	System	24 Aug 2020 19:30:47



US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Aug 2020 15:21'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Aug 2020 17:51'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:10:01', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '04ec4f2f-c465-47b3-891b-b175f313356a'	System	25 Aug 2020 02:11:08
User entered 'None (1)'	System	25 Aug 2020 02:11:08

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:10:11', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '04ec4f2f-c465-47b3-891b-b175f313356a'	System	25 Aug 2020 02:11:08
User entered 'No (N)'	System	25 Aug 2020 02:11:08

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:10:50', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '04ec4f2f-c465-47b3-891b-b175f313356a'	System	25 Aug 2020 02:11:08
User entered 'No (N)'	System	25 Aug 2020 02:11:08

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:10:41', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '04ec4f2f-c465-47b3-891b-b175f313356a'	System	25 Aug 2020 02:11:08
User entered 'None (1)'	System	25 Aug 2020 02:11:08

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:11:05', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '04ec4f2f-c465-47b3-891b-b175f313356a'	System	25 Aug 2020 02:11:08
User entered '24 Aug 2020 22:11'	System	25 Aug 2020 02:11:08



US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Aug 2020 18:46'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 2'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:17:09', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '01cdafed-025c-4062-a46b-834f0e9b0417'	System	25 Aug 2020 23:17:43
User entered 'None (1)'	System	25 Aug 2020 23:17:43

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:17:14', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '01cdafed-025c-4062-a46b-834f0e9b0417'	System	25 Aug 2020 23:17:43
User entered 'No (N)'	System	25 Aug 2020 23:17:43

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:17:21', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '01cdafed-025c-4062-a46b-834f0e9b0417'	System	25 Aug 2020 23:17:43
User entered 'No (N)'	System	25 Aug 2020 23:17:43

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:17:28', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '01cdafed-025c-4062-a46b-834f0e9b0417'	System	25 Aug 2020 23:17:43
User entered 'None (1)'	System	25 Aug 2020 23:17:43

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:17:39', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '01cdafed-025c-4062-a46b-834f0e9b0417'	System	25 Aug 2020 23:17:43
User entered '25 Aug 2020 19:17'	System	25 Aug 2020 23:17:43



US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 3'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:55:20', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'c8d0cea9-aa11-4d3e-922a-2e86b04a64c2'	System	27 Aug 2020 01:56:56
User entered 'None (1)'	System	27 Aug 2020 01:56:56

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:56:36', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'c8d0cea9-aa11-4d3e-922a-2e86b04a64c2'	System	27 Aug 2020 01:56:56
User entered 'No (N)'	System	27 Aug 2020 01:56:56

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:56:41', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'c8d0cea9-aa11-4d3e-922a-2e86b04a64c2'	System	27 Aug 2020 01:56:56
User entered 'No (N)'	System	27 Aug 2020 01:56:56

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:56:46', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'c8d0cea9-aa11-4d3e-922a-2e86b04a64c2'	System	27 Aug 2020 01:56:56
User entered 'None (1)'	System	27 Aug 2020 01:56:56

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:56:51', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'c8d0cea9-aa11-4d3e-922a-2e86b04a64c2'	System	27 Aug 2020 01:56:56
User entered '26 Aug 2020 21:56'	System	27 Aug 2020 01:56:56



US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 4'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25



US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 5'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:37:32', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f340a257-c06a-4d0a-a654-9b48e218c4dc'	System	29 Aug 2020 01:38:08
User entered 'None (1)'	System	29 Aug 2020 01:38:08

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:37:39', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f340a257-c06a-4d0a-a654-9b48e218c4dc'	System	29 Aug 2020 01:38:08
User entered 'No (N)'	System	29 Aug 2020 01:38:08

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:37:49', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f340a257-c06a-4d0a-a654-9b48e218c4dc'	System	29 Aug 2020 01:38:08
User entered 'No (N)'	System	29 Aug 2020 01:38:08



US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:38:00', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f340a257-c06a-4d0a-a654-9b48e218c4dc'	System	29 Aug 2020 01:38:08
User entered 'None (1)'	System	29 Aug 2020 01:38:08

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:38:04', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f340a257-c06a-4d0a-a654-9b48e218c4dc'	System	29 Aug 2020 01:38:08
User entered '28 Aug 2020 21:38'	System	29 Aug 2020 01:38:08

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 6'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25



US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 7'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:23:05', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '06869bc0-f373-428a-b5da-2125cba0c590'	System	31 Aug 2020 03:23:41
User entered 'None (1)'	System	31 Aug 2020 03:23:41



US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:23:08', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '06869bc0-f373-428a-b5da-2125cba0c590'	System	31 Aug 2020 03:23:41
User entered 'No (N)'	System	31 Aug 2020 03:23:41

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:23:17', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '06869bc0-f373-428a-b5da-2125cba0c590'	System	31 Aug 2020 03:23:41
User entered 'No (N)'	System	31 Aug 2020 03:23:41

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:23:20', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '06869bc0-f373-428a-b5da-2125cba0c590'	System	31 Aug 2020 03:23:41
User entered 'None (1)'	System	31 Aug 2020 03:23:41

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:23:37', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '06869bc0-f373-428a-b5da-2125cba0c590'	System	31 Aug 2020 03:23:41
User entered '30 Aug 2020 23:23'	System	31 Aug 2020 03:23:41

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:30:47', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '62830366-4899-4fd6-b3a2-e65747acc2b6'	System	24 Aug 2020 19:31:20
User entered 'None (0)'	System	24 Aug 2020 19:31:20



US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:30:51', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '62830366-4899-4fd6-b3a2-e65747acc2b6'	System	24 Aug 2020 19:31:20
User entered 'None (0)'	System	24 Aug 2020 19:31:20

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:30:55', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '62830366-4899-4fd6-b3a2-e65747acc2b6'	System	24 Aug 2020 19:31:20
User entered 'None (0)'	System	24 Aug 2020 19:31:20

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:30:59', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '62830366-4899-4fd6-b3a2-e65747acc2b6'	System	24 Aug 2020 19:31:20
User entered 'None (0)'	System	24 Aug 2020 19:31:20

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:31:03', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '62830366-4899-4fd6-b3a2-e65747acc2b6'	System	24 Aug 2020 19:31:20
User entered 'None (0)'	System	24 Aug 2020 19:31:20

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:31:06', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '62830366-4899-4fd6-b3a2-e65747acc2b6'	System	24 Aug 2020 19:31:20
User entered 'None (0)'	System	24 Aug 2020 19:31:20

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:31:11', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '62830366-4899-4fd6-b3a2-e65747acc2b6'	System	24 Aug 2020 19:31:20
User entered 'No (N)'	System	24 Aug 2020 19:31:20

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T15:31:14', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '62830366-4899-4fd6-b3a2-e65747acc2b6'	System	24 Aug 2020 19:31:20
User entered '24 Aug 2020 15:31'	System	24 Aug 2020 19:31:20

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Aug 2020 15:21'	System	24 Aug 2020 19:13:39



US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Aug 2020 17:51'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:11:15', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8b9175dc-51f9-4a95-9bb8-7ce4f41ebb7d'	System	25 Aug 2020 02:12:17
User entered 'None (0)'	System	25 Aug 2020 02:12:17

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:11:22', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8b9175dc-51f9-4a95-9bb8-7ce4f41ebb7d'	System	25 Aug 2020 02:12:17
User entered 'None (0)'	System	25 Aug 2020 02:12:17

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:11:30', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8b9175dc-51f9-4a95-9bb8-7ce4f41ebb7d'	System	25 Aug 2020 02:12:17
User entered 'None (0)'	System	25 Aug 2020 02:12:17

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:11:39', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8b9175dc-51f9-4a95-9bb8-7ce4f41ebb7d'	System	25 Aug 2020 02:12:17
User entered 'None (0)'	System	25 Aug 2020 02:12:17

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:11:44', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8b9175dc-51f9-4a95-9bb8-7ce4f41ebb7d'	System	25 Aug 2020 02:12:17
User entered 'None (0)'	System	25 Aug 2020 02:12:17

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:11:50', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8b9175dc-51f9-4a95-9bb8-7ce4f41ebb7d'	System	25 Aug 2020 02:12:17
User entered 'None (0)'	System	25 Aug 2020 02:12:17



US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:12:00', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8b9175dc-51f9-4a95-9bb8-7ce4f41ebb7d'	System	25 Aug 2020 02:12:17
User entered 'No (N)'	System	25 Aug 2020 02:12:17

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-24T22:12:13', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8b9175dc-51f9-4a95-9bb8-7ce4f41ebb7d'	System	25 Aug 2020 02:12:17
User entered '24 Aug 2020 22:12'	System	25 Aug 2020 02:12:17

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Aug 2020 18:46'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 2'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:17:50', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7593cd1-1a78-4cf9-81af-75b8d51920a5'	System	25 Aug 2020 23:18:34
User entered 'None (0)'	System	25 Aug 2020 23:18:34

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:17:56', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7593cd1-1a78-4cf9-81af-75b8d51920a5'	System	25 Aug 2020 23:18:34
User entered 'None (0)'	System	25 Aug 2020 23:18:34

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:18:01', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7593cd1-1a78-4cf9-81af-75b8d51920a5'	System	25 Aug 2020 23:18:34
User entered 'None (0)'	System	25 Aug 2020 23:18:34



US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:18:06', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7593cd1-1a78-4cf9-81af-75b8d51920a5'	System	25 Aug 2020 23:18:34
User entered 'None (0)'	System	25 Aug 2020 23:18:34

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:18:10', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7593cd1-1a78-4cf9-81af-75b8d51920a5'	System	25 Aug 2020 23:18:34
User entered 'None (0)'	System	25 Aug 2020 23:18:34

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:18:15', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7593cd1-1a78-4cf9-81af-75b8d51920a5'	System	25 Aug 2020 23:18:34
User entered 'None (0)'	System	25 Aug 2020 23:18:34

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:18:21', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7593cd1-1a78-4cf9-81af-75b8d51920a5'	System	25 Aug 2020 23:18:34
User entered 'No (N)'	System	25 Aug 2020 23:18:34

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-25T19:18:29', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7593cd1-1a78-4cf9-81af-75b8d51920a5'	System	25 Aug 2020 23:18:34
User entered '25 Aug 2020 19:18'	System	25 Aug 2020 23:18:34

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 3'	System	24 Aug 2020 19:13:39



US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:57:04', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '4b602de5-d825-4a2c-b5a7-3f2a51732308'	System	27 Aug 2020 01:57:48
User entered 'None (0)'	System	27 Aug 2020 01:57:48

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:57:13', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '4b602de5-d825-4a2c-b5a7-3f2a51732308'	System	27 Aug 2020 01:57:48
User entered 'None (0)'	System	27 Aug 2020 01:57:48

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:57:18', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '4b602de5-d825-4a2c-b5a7-3f2a51732308'	System	27 Aug 2020 01:57:48
User entered 'None (0)'	System	27 Aug 2020 01:57:48

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:57:23', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '4b602de5-d825-4a2c-b5a7-3f2a51732308'	System	27 Aug 2020 01:57:48
User entered 'None (0)'	System	27 Aug 2020 01:57:48

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:57:27', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '4b602de5-d825-4a2c-b5a7-3f2a51732308'	System	27 Aug 2020 01:57:48
User entered 'None (0)'	System	27 Aug 2020 01:57:48

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:57:31', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '4b602de5-d825-4a2c-b5a7-3f2a51732308'	System	27 Aug 2020 01:57:48
User entered 'None (0)'	System	27 Aug 2020 01:57:48

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:57:38', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '4b602de5-d825-4a2c-b5a7-3f2a51732308'	System	27 Aug 2020 01:57:48
User entered 'No (N)'	System	27 Aug 2020 01:57:48

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-26T21:57:43', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '4b602de5-d825-4a2c-b5a7-3f2a51732308'	System	27 Aug 2020 01:57:48
User entered '26 Aug 2020 21:57'	System	27 Aug 2020 01:57:48



US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 4'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25



US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 5'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:38:10', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '668136a7-69fd-41c7-965e-3b213797bc5d'	System	29 Aug 2020 01:38:53
User entered 'None (0)'	System	29 Aug 2020 01:38:53

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:38:17', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '668136a7-69fd-41c7-965e-3b213797bc5d'	System	29 Aug 2020 01:38:53
User entered 'None (0)'	System	29 Aug 2020 01:38:53



US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:38:22', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '668136a7-69fd-41c7-965e-3b213797bc5d'	System	29 Aug 2020 01:38:53
User entered 'None (0)'	System	29 Aug 2020 01:38:53

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:38:27', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '668136a7-69fd-41c7-965e-3b213797bc5d'	System	29 Aug 2020 01:38:53
User entered 'None (0)'	System	29 Aug 2020 01:38:53

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:38:31', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '668136a7-69fd-41c7-965e-3b213797bc5d'	System	29 Aug 2020 01:38:53
User entered 'None (0)'	System	29 Aug 2020 01:38:53

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:38:35', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '668136a7-69fd-41c7-965e-3b213797bc5d'	System	29 Aug 2020 01:38:53
User entered 'None (0)'	System	29 Aug 2020 01:38:53

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:38:43', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '668136a7-69fd-41c7-965e-3b213797bc5d'	System	29 Aug 2020 01:38:53
User entered 'No (N)'	System	29 Aug 2020 01:38:53

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-28T21:38:49', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '668136a7-69fd-41c7-965e-3b213797bc5d'	System	29 Aug 2020 01:38:53
User entered '28 Aug 2020 21:38'	System	29 Aug 2020 01:38:53

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 19:13:39



US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 6'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

**US3222311**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:07:28**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25



US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 7'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:23:50', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '625ebcec-6e9b-4b15-ba26-18b99d262b4a'	System	31 Aug 2020 03:24:18
User entered 'None (0)'	System	31 Aug 2020 03:24:18

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:23:53', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '625ebcec-6e9b-4b15-ba26-18b99d262b4a'	System	31 Aug 2020 03:24:18
User entered 'None (0)'	System	31 Aug 2020 03:24:18

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:23:55', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '625ebcec-6e9b-4b15-ba26-18b99d262b4a'	System	31 Aug 2020 03:24:18
User entered 'None (0)'	System	31 Aug 2020 03:24:18

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:24:03', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '625ebcec-6e9b-4b15-ba26-18b99d262b4a'	System	31 Aug 2020 03:24:18
User entered 'None (0)'	System	31 Aug 2020 03:24:18



US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:24:07', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '625ebcec-6e9b-4b15-ba26-18b99d262b4a'	System	31 Aug 2020 03:24:18
User entered 'None (0)'	System	31 Aug 2020 03:24:18

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:24:09', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '625ebcec-6e9b-4b15-ba26-18b99d262b4a'	System	31 Aug 2020 03:24:18
User entered 'None (0)'	System	31 Aug 2020 03:24:18

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:24:12', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '625ebcec-6e9b-4b15-ba26-18b99d262b4a'	System	31 Aug 2020 03:24:18
User entered 'No (N)'	System	31 Aug 2020 03:24:18

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-08-30T23:24:16', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '625ebcec-6e9b-4b15-ba26-18b99d262b4a'	System	31 Aug 2020 03:24:18
User entered '30 Aug 2020 23:24'	System	31 Aug 2020 03:24:18

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 19:13:39

US3222311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 16:55:04

US3222311

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '31 Aug 2020'	Crystal Paccione (b) (4)	23 Sep 2020 16:55:04



US3222311

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 16:55:04

US3222311

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 16:55:04

US3222311

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 16:55:13

US3222311

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'I'	System	23 Sep 2020 16:55:13

US3222311

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	23 Sep 2020 16:55:36

US3222311

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '07 Sep 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Nov 2020 16:24:50
User entered '7 Sep 2020'	Crystal Paccione (b) (4)	23 Sep 2020 16:55:36

US3222311

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 16:55:36

US3222311

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 16:55:36



US3222311

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 16:55:51

**US3222311**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'I'	System	23 Sep 2020 16:55:51

US3222311

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	23 Sep 2020 16:56:10

US3222311

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '14 Sep 2020'	Crystal Paccione (b) (4)	23 Sep 2020 16:56:10

US3222311

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 16:56:10

US3222311

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 16:56:10

US3222311

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 16:56:16

US3222311

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'I'	System	23 Sep 2020 16:56:16



US3222311

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 16:56:53

US3222311

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '23 Sep 2020'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 16:56:53

US3222311

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Clinic (Clinic)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	23 Sep 2020 16:56:53

US3222311

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'VISIT2'	System	23 Sep 2020 16:56:53

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '23 Sep 2020'	Albert Garcia (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '12:08'	Albert Garcia (b) (4)	29 Sep 2020 13:47:21



US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered '23 Sep 2020 12:08'	System	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '37.0' C	Albert Garcia (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	Albert Garcia (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '73'	Albert Garcia (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'bpm'	System	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '16'	Albert Garcia (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'breaths/min'	System	29 Sep 2020 13:47:21



US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '125'	Albert Garcia (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'mmHg'	System	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '85'	Albert Garcia (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'mmHg'	System	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Sep 2020 13:47:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Sep 2020 13:47:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Albert Garcia (b) (4)	29 Sep 2020 13:47:33
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Sep 2020 13:47:21
User entered empty.	System	29 Sep 2020 13:47:21
	Albert Garcia (b) (4)	29 Sep 2020 13:47:21
	(b) (4)	

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '23 Sep 2020'	Albert Garcia (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '12:34'	Albert Garcia (b) (4)	29 Sep 2020 13:47:21



**US3222311**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered '23 Sep 2020 12:34'	System	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '36.7' C	Albert Garcia (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Oral (Oral)'	(b) (4) Albert Garcia (b) (4) (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '65'	Albert Garcia (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'bpm'	System	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '16'	Albert Garcia (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'breaths/min'	System	29 Sep 2020 13:47:21



US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '140'	Albert Garcia (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'mmHg'	System	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '80'	Albert Garcia (b) (4)	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'mmHg'	System	29 Sep 2020 13:47:21

US3222311

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	Albert Garcia (b) (4)	29 Sep 2020 13:47:39

US3222311

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '23 Sep 2020'	Albert Garcia (b) (4)	29 Sep 2020 13:47:39

US3222311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 16:57:19

US3222311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) Crystal Paccione (b) (4)	23 Sep 2020 16:57:19



US3222311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

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)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	Crystal Paccione (b) (4)	23 Sep 2020 16:57:19

US3222311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 16:57:19

US3222311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '23 Sep 2020'	Crystal Paccione (b) (4)	23 Sep 2020 16:57:19

US3222311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '12:51'	(b) (4) Crystal Paccione (b) (4) (b) (4)	23 Sep 2020 16:57:19

US3222311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered '23 Sep 2020 12:51'	System	23 Sep 2020 16:57:19

US3222311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Left Arm (LEFT ARM)'	Crystal Paccione (b) (4)	23 Sep 2020 16:57:19

US3222311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'ONCE'	System	23 Sep 2020 16:57:19

US3222311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 16:57:19



US3222311

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
Query 'Per GCL Lab Recon: Sample was reported under Visit 3 Day 57 dated 20Oct2020 in PPD Central lab; however Visit 3 is missing in EDC. Please reconcile.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 11:32:57
User opened query 'Per GCL Lab Recon: Sample was reported under Visit 3 Day 57 dated 20Oct2020 in PPD Central lab; however Visit 3 is missing in EDC. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:26:12
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	29 Sep 2020 13:47:58

US3222311

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 11:32:08
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify.' answered with 'Per PRECLARS these samples were rec'd.' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	21 Oct 2020 14:08:01
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 23SEP2020; however, it has not been received by GCL. Please clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 17:43:01
User entered '23 Sep 2020'	Albert Garcia (b) (4) (b) (4)	29 Sep 2020 13:47:58

US3222311

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '12:18'	Albert Garcia (b) (4)	29 Sep 2020 13:47:58

**US3222311**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:07:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered '23 Sep 2020 12:18'	System	29 Sep 2020 13:47:58

US3222311

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:07:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '23 Sep 2020'	Albert Garcia (b) (4)	29 Sep 2020 13:48:15

**US3222311**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	29 Sep 2020 13:48:15

US3222311

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:07:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	Albert Garcia (b) (4)	29 Sep 2020 13:48:15

**US3222311**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:07:28**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '12:15'	Albert Garcia (b) (4)	29 Sep 2020 13:48:15



**US3222311**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered '23 Sep 2020 12:15'	System	29 Sep 2020 13:48:15

US3222311

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:07:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	29 Sep 2020 13:48:15

US3222311

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:07:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	Albert Garcia (b) (4)	29 Sep 2020 13:48:15

US3222311

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:07:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	Albert Garcia (b) (4)	29 Sep 2020 13:48:15

**US3222311**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered empty.	System	29 Sep 2020 13:48:15

US3222311

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4) (b) (4)	29 Sep 2020 13:48:38

US3222311

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'I'	System	29 Sep 2020 13:48:38

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 16:57:19



US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:20:26', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'c9e615de-67b8-4555-8492-8236822578f0'	System	23 Sep 2020 17:20:46
User entered 'Yes (Y)'	System	23 Sep 2020 17:20:46

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:20:31', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'c9e615de-67b8-4555-8492-8236822578f0'	System	23 Sep 2020 17:20:46
User entered '98.0'	System	23 Sep 2020 17:20:46

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:20:38', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'c9e615de-67b8-4555-8492-8236822578f0'	System	23 Sep 2020 17:20:46
User entered 'No (N)'	System	23 Sep 2020 17:20:46

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:20:41', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'c9e615de-67b8-4555-8492-8236822578f0'	System	23 Sep 2020 17:20:46
User entered '23 Sep 2020 13:20'	System	23 Sep 2020 17:20:46

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '23 Sep 2020 13:11'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '23 Sep 2020 15:41'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:22:13', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '2856d6cb-869c-4b82-89e9-71e49ddc5803'	System	24 Sep 2020 02:22:28
User entered 'Yes (Y)'	System	24 Sep 2020 02:22:28



US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:22:19', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '2856d6cb-869c-4b82-89e9-71e49ddc5803'	System	24 Sep 2020 02:22:28
User entered '97.7'	System	24 Sep 2020 02:22:28

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:22:23', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '2856d6cb-869c-4b82-89e9-71e49ddc5803'	System	24 Sep 2020 02:22:28
User entered 'No (N)'	System	24 Sep 2020 02:22:28

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:22:26', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '2856d6cb-869c-4b82-89e9-71e49ddc5803'	System	24 Sep 2020 02:22:28
User entered '23 Sep 2020 22:22'	System	24 Sep 2020 02:22:28

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '23 Sep 2020 16:36'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 2'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:32:25', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '254ac711-e5e6-47ff-8d1f-b508f51fa0b2'	System	25 Sep 2020 02:32:42
User entered 'Yes (Y)'	System	25 Sep 2020 02:32:42

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:32:34', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '254ac711-e5e6-47ff-8d1f-b508f51fa0b2'	System	25 Sep 2020 02:32:42
User entered '98.2'	System	25 Sep 2020 02:32:42



US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:32:38', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '254ac711-e5e6-47ff-8d1f-b508f51fa0b2'	System	25 Sep 2020 02:32:42
User entered 'No (N)'	System	25 Sep 2020 02:32:42

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:32:40', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '254ac711-e5e6-47ff-8d1f-b508f51fa0b2'	System	25 Sep 2020 02:32:42
User entered '24 Sep 2020 22:32'	System	25 Sep 2020 02:32:42

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 3'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:51:00', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f7dc5980-653c-4f4d-82cd-0fc149d8ec39'	System	26 Sep 2020 01:51:15
User entered 'Yes (Y)'	System	26 Sep 2020 01:51:15

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:51:06', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f7dc5980-653c-4f4d-82cd-0fc149d8ec39'	System	26 Sep 2020 01:51:15
User entered '98.7'	System	26 Sep 2020 01:51:15

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:51:09', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f7dc5980-653c-4f4d-82cd-0fc149d8ec39'	System	26 Sep 2020 01:51:15
User entered 'No (N)'	System	26 Sep 2020 01:51:15



US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:51:12', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f7dc5980-653c-4f4d-82cd-0fc149d8ec39'	System	26 Sep 2020 01:51:15
User entered '25 Sep 2020 21:51'	System	26 Sep 2020 01:51:15

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 4'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:04:49', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'd8fbc736-7f22-4e0a-acf2-19d2a9ed23f2'	System	27 Sep 2020 03:05:04
User entered 'Yes (Y)'	System	27 Sep 2020 03:05:04

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:04:55', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'd8fbc736-7f22-4e0a-acf2-19d2a9ed23f2'	System	27 Sep 2020 03:05:04
User entered '98.6'	System	27 Sep 2020 03:05:04

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:04:58', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'd8fbc736-7f22-4e0a-acf2-19d2a9ed23f2'	System	27 Sep 2020 03:05:04
User entered 'No (N)'	System	27 Sep 2020 03:05:04

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:05:02', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'd8fbc736-7f22-4e0a-acf2-19d2a9ed23f2'	System	27 Sep 2020 03:05:04
User entered '26 Sep 2020 23:05'	System	27 Sep 2020 03:05:04



**US3222311**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:07:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 5'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:01:30', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '3fac578f-02d0-4539-92ad-39a66defa1ce'	System	28 Sep 2020 00:01:49
User entered 'Yes (Y)'	System	28 Sep 2020 00:01:49

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:01:35', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '3fac578f-02d0-4539-92ad-39a66defa1ce' User entered '99.9'	System	28 Sep 2020 00:01:49
	System	28 Sep 2020 00:01:49

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:01:40', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '3fac578f-02d0-4539-92ad-39a66defa1ce'	System	28 Sep 2020 00:01:49
User entered 'No (N)'	System	28 Sep 2020 00:01:49

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:01:46', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '3fac578f-02d0-4539-92ad-39a66defa1ce'	System	28 Sep 2020 00:01:49
User entered '27 Sep 2020 20:01'	System	28 Sep 2020 00:01:49

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 16:57:19



US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 6'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25



US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 7'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T16:59:12', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '7faa0979-28b5-44d8-aa5d-4e99482d38a8'	System	29 Sep 2020 21:00:07
User entered 'Yes (Y)'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T16:59:20', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '7faa0979-28b5-44d8-aa5d-4e99482d38a8'	System	29 Sep 2020 21:00:07
User entered '99.8'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T16:59:32', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '7faa0979-28b5-44d8-aa5d-4e99482d38a8'	System	29 Sep 2020 21:00:07
User entered 'Yes (Y)'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'ALL INFORMATION IS NOTED IN SAE REPORT.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 10:19:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Albert Garcia (b) (4)	10 Nov 2020 20:17:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T16:59:49', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '7faa0979-28b5-44d8-aa5d-4e99482d38a8'	System	29 Sep 2020 21:00:07
User entered '1'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T16:59:49', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '7faa0979-28b5-44d8-aa5d-4e99482d38a8'	System	29 Sep 2020 21:00:07
User entered '0'	System	29 Sep 2020 21:00:07



US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T16:59:57', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '7faa0979-28b5-44d8-aa5d-4e99482d38a8'	System	29 Sep 2020 21:00:07
User entered '29 Sep 2020 16:59'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	29 Sep 2020 21:00:07
User entered 'Day 8'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25



US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:07:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	29 Sep 2020 21:00:07
User entered 'Day 9'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:07:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:07:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25



US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:07:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:20:48', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'bda77f0d-a20d-467b-9f40-3cdadc8f3fc5'	System	23 Sep 2020 17:21:21
User entered 'None (1)'	System	23 Sep 2020 17:21:21

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:21:00', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'bda77f0d-a20d-467b-9f40-3cdadc8f3fc5'	System	23 Sep 2020 17:21:21
User entered 'No (N)'	System	23 Sep 2020 17:21:21



US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:21:05', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'bda77f0d-a20d-467b-9f40-3cdadc8f3fc5'	System	23 Sep 2020 17:21:21
User entered 'No (N)'	System	23 Sep 2020 17:21:21

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:21:14', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'bda77f0d-a20d-467b-9f40-3cdadc8f3fc5'	System	23 Sep 2020 17:21:21
User entered 'None (1)'	System	23 Sep 2020 17:21:21

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:21:16', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'bda77f0d-a20d-467b-9f40-3cdadc8f3fc5'	System	23 Sep 2020 17:21:21
User entered '23 Sep 2020 13:21'	System	23 Sep 2020 17:21:21

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '23 Sep 2020 13:11'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '23 Sep 2020 15:41'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:22:36', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '6387bad3-ba1f-4e21-b227-8f0ee0adf678'	System	24 Sep 2020 02:23:13
User entered 'None (1)'	System	24 Sep 2020 02:23:13

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:22:43', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '6387bad3-ba1f-4e21-b227-8f0ee0adf678'	System	24 Sep 2020 02:23:13
User entered 'No (N)'	System	24 Sep 2020 02:23:13



US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:22:53', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '6387bad3-ba1f-4e21-b227-8f0ee0adf678'	System	24 Sep 2020 02:23:13
User entered 'No (N)'	System	24 Sep 2020 02:23:13

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:23:05', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '6387bad3-ba1f-4e21-b227-8f0ee0adf678'	System	24 Sep 2020 02:23:13
User entered 'None (1)'	System	24 Sep 2020 02:23:13

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:23:10', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '6387bad3-ba1f-4e21-b227-8f0ee0adf678'	System	24 Sep 2020 02:23:13
User entered '23 Sep 2020 22:23'	System	24 Sep 2020 02:23:13

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '23 Sep 2020 16:36'	System	23 Sep 2020 16:57:19

**US3222311**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:07:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 2'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:32:52', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7e15e14-c31f-4839-b493-425587598bb7'	System	25 Sep 2020 02:33:34
User entered 'None (1)'	System	25 Sep 2020 02:33:34

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:32:59', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7e15e14-c31f-4839-b493-425587598bb7'	System	25 Sep 2020 02:33:34
User entered 'No (N)'	System	25 Sep 2020 02:33:34



US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:33:08', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7e15e14-c31f-4839-b493-425587598bb7'	System	25 Sep 2020 02:33:34
User entered 'No (N)'	System	25 Sep 2020 02:33:34

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:33:25', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7e15e14-c31f-4839-b493-425587598bb7'	System	25 Sep 2020 02:33:34
User entered 'None (1)'	System	25 Sep 2020 02:33:34

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:33:30', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7e15e14-c31f-4839-b493-425587598bb7'	System	25 Sep 2020 02:33:34
User entered '24 Sep 2020 22:33'	System	25 Sep 2020 02:33:34

**US3222311**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:07:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 3'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:51:23', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '38d89466-f835-46dc-bde9-4349402b97a6'	System	26 Sep 2020 01:51:54
User entered 'None (1)'	System	26 Sep 2020 01:51:54

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:51:36', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '38d89466-f835-46dc-bde9-4349402b97a6'	System	26 Sep 2020 01:51:54
User entered 'No (N)'	System	26 Sep 2020 01:51:54



US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:51:41', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '38d89466-f835-46dc-bde9-4349402b97a6'	System	26 Sep 2020 01:51:54
User entered 'No (N)'	System	26 Sep 2020 01:51:54

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:51:47', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '38d89466-f835-46dc-bde9-4349402b97a6'	System	26 Sep 2020 01:51:54
User entered 'None (1)'	System	26 Sep 2020 01:51:54

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:51:51', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '38d89466-f835-46dc-bde9-4349402b97a6'	System	26 Sep 2020 01:51:54
User entered '25 Sep 2020 21:51'	System	26 Sep 2020 01:51:54

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 4'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:05:08', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'ff2ff69a-7d7f-487f-919a-21076a274289'	System	27 Sep 2020 03:06:00
User entered 'None (1)'	System	27 Sep 2020 03:06:00

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:05:12', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'ff2ff69a-7d7f-487f-919a-21076a274289'	System	27 Sep 2020 03:06:00
User entered 'No (N)'	System	27 Sep 2020 03:06:00



US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:05:48', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'ff2ff69a-7d7f-487f-919a-21076a274289'	System	27 Sep 2020 03:06:00
User entered 'No (N)'	System	27 Sep 2020 03:06:00

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:05:53', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'ff2ff69a-7d7f-487f-919a-21076a274289'	System	27 Sep 2020 03:06:00
User entered 'None (1)'	System	27 Sep 2020 03:06:00

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:05:57', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'ff2ff69a-7d7f-487f-919a-21076a274289'	System	27 Sep 2020 03:06:00
User entered '26 Sep 2020 23:05'	System	27 Sep 2020 03:06:00

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

**US3222311**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:07:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 5'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:01:53', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'a02395b1-7af7-443a-8759-a15f9d8654bc'	System	28 Sep 2020 00:02:28
User entered 'None (1)'	System	28 Sep 2020 00:02:28

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:01:56', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'a02395b1-7af7-443a-8759-a15f9d8654bc'	System	28 Sep 2020 00:02:28
User entered 'No (N)'	System	28 Sep 2020 00:02:28



US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:02:04', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'a02395b1-7af7-443a-8759-a15f9d8654bc'	System	28 Sep 2020 00:02:28
User entered 'No (N)'	System	28 Sep 2020 00:02:28

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:02:19', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'a02395b1-7af7-443a-8759-a15f9d8654bc'	System	28 Sep 2020 00:02:28
User entered 'None (1)'	System	28 Sep 2020 00:02:28

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:02:25', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'a02395b1-7af7-443a-8759-a15f9d8654bc'	System	28 Sep 2020 00:02:28
User entered '27 Sep 2020 20:02'	System	28 Sep 2020 00:02:28

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

**US3222311**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:07:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 6'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25



US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 7'	System	23 Sep 2020 16:57:19



US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T17:00:07', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f170f3a2-92f3-4546-861b-c7ce8bc36866'	System	29 Sep 2020 21:00:24
User entered 'None (1)'	System	29 Sep 2020 21:00:24

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T17:00:10', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f170f3a2-92f3-4546-861b-c7ce8bc36866'	System	29 Sep 2020 21:00:24
User entered 'No (N)'	System	29 Sep 2020 21:00:24

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T17:00:13', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f170f3a2-92f3-4546-861b-c7ce8bc36866'	System	29 Sep 2020 21:00:24
User entered 'No (N)'	System	29 Sep 2020 21:00:24

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T17:00:18', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f170f3a2-92f3-4546-861b-c7ce8bc36866'	System	29 Sep 2020 21:00:24
User entered 'None (1)'	System	29 Sep 2020 21:00:24

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T17:00:20', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f170f3a2-92f3-4546-861b-c7ce8bc36866'	System	29 Sep 2020 21:00:24
User entered '29 Sep 2020 17:00'	System	29 Sep 2020 21:00:24

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 16:57:19



US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:21:22', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f8f768d8-a565-42d5-87ae-c12bce8e800d'	System	23 Sep 2020 17:21:55
User entered 'None (0)'	System	23 Sep 2020 17:21:55

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:21:27', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f8f768d8-a565-42d5-87ae-c12bce8e800d'	System	23 Sep 2020 17:21:55
User entered 'None (0)'	System	23 Sep 2020 17:21:55

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:21:32', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f8f768d8-a565-42d5-87ae-c12bce8e800d'	System	23 Sep 2020 17:21:55
User entered 'None (0)'	System	23 Sep 2020 17:21:55

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:21:37', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f8f768d8-a565-42d5-87ae-c12bce8e800d'	System	23 Sep 2020 17:21:55
User entered 'None (0)'	System	23 Sep 2020 17:21:55

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:21:41', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f8f768d8-a565-42d5-87ae-c12bce8e800d'	System	23 Sep 2020 17:21:55
User entered 'None (0)'	System	23 Sep 2020 17:21:55

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:21:45', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f8f768d8-a565-42d5-87ae-c12bce8e800d'	System	23 Sep 2020 17:21:55
User entered 'None (0)'	System	23 Sep 2020 17:21:55

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:21:50', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f8f768d8-a565-42d5-87ae-c12bce8e800d'	System	23 Sep 2020 17:21:55
User entered 'No (N)'	System	23 Sep 2020 17:21:55

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T13:21:52', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f8f768d8-a565-42d5-87ae-c12bce8e800d'	System	23 Sep 2020 17:21:55
User entered '23 Sep 2020 13:21'	System	23 Sep 2020 17:21:55



US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '23 Sep 2020 13:11'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '23 Sep 2020 15:41'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:23:15', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '807ce472-3831-416e-86ba-9ac6b69855a4'	System	24 Sep 2020 02:23:57
User entered 'None (0)'	System	24 Sep 2020 02:23:57

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:23:20', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '807ce472-3831-416e-86ba-9ac6b69855a4'	System	24 Sep 2020 02:23:57
User entered 'None (0)'	System	24 Sep 2020 02:23:57

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:23:25', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '807ce472-3831-416e-86ba-9ac6b69855a4'	System	24 Sep 2020 02:23:57
User entered 'None (0)'	System	24 Sep 2020 02:23:57

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:23:34', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '807ce472-3831-416e-86ba-9ac6b69855a4'	System	24 Sep 2020 02:23:57
User entered 'None (0)'	System	24 Sep 2020 02:23:57

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:23:39', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '807ce472-3831-416e-86ba-9ac6b69855a4'	System	24 Sep 2020 02:23:57
User entered 'None (0)'	System	24 Sep 2020 02:23:57



US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:23:43', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '807ce472-3831-416e-86ba-9ac6b69855a4'	System	24 Sep 2020 02:23:57
User entered 'None (0)'	System	24 Sep 2020 02:23:57

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:23:52', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '807ce472-3831-416e-86ba-9ac6b69855a4'	System	24 Sep 2020 02:23:57
User entered 'No (N)'	System	24 Sep 2020 02:23:57

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-23T22:23:55', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '807ce472-3831-416e-86ba-9ac6b69855a4'	System	24 Sep 2020 02:23:57
User entered '23 Sep 2020 22:23'	System	24 Sep 2020 02:23:57

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '23 Sep 2020 16:36'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 2'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:33:36', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '7c2d924b-1bc1-4b1b-808b-b9cc902a8070'	System	25 Sep 2020 02:34:11
User entered 'None (0)'	System	25 Sep 2020 02:34:11

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:33:41', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '7c2d924b-1bc1-4b1b-808b-b9cc902a8070'	System	25 Sep 2020 02:34:11
User entered 'None (0)'	System	25 Sep 2020 02:34:11



US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:33:46', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '7c2d924b-1bc1-4b1b-808b-b9cc902a8070'	System	25 Sep 2020 02:34:11
User entered 'None (0)'	System	25 Sep 2020 02:34:11

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:33:52', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '7c2d924b-1bc1-4b1b-808b-b9cc902a8070'	System	25 Sep 2020 02:34:11
User entered 'None (0)'	System	25 Sep 2020 02:34:11

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:33:56', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '7c2d924b-1bc1-4b1b-808b-b9cc902a8070'	System	25 Sep 2020 02:34:11
User entered 'None (0)'	System	25 Sep 2020 02:34:11

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:34:00', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '7c2d924b-1bc1-4b1b-808b-b9cc902a8070'	System	25 Sep 2020 02:34:11
User entered 'None (0)'	System	25 Sep 2020 02:34:11

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:34:05', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '7c2d924b-1bc1-4b1b-808b-b9cc902a8070'	System	25 Sep 2020 02:34:11
User entered 'No (N)'	System	25 Sep 2020 02:34:11

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-24T22:34:09', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '7c2d924b-1bc1-4b1b-808b-b9cc902a8070'	System	25 Sep 2020 02:34:11
User entered '24 Sep 2020 22:34'	System	25 Sep 2020 02:34:11

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 16:57:19



US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 3'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:51:55', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '0e91c6f7-c370-473b-aec2-06ae8e2eb05a'	System	26 Sep 2020 01:52:27
User entered 'None (0)'	System	26 Sep 2020 01:52:27

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:51:59', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '0e91c6f7-c370-473b-aec2-06ae8e2eb05a'	System	26 Sep 2020 01:52:27
User entered 'None (0)'	System	26 Sep 2020 01:52:27

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:52:04', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '0e91c6f7-c370-473b-aec2-06ae8e2eb05a'	System	26 Sep 2020 01:52:27
User entered 'None (0)'	System	26 Sep 2020 01:52:27

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:52:08', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '0e91c6f7-c370-473b-aec2-06ae8e2eb05a'	System	26 Sep 2020 01:52:27
User entered 'None (0)'	System	26 Sep 2020 01:52:27

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:52:12', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '0e91c6f7-c370-473b-aec2-06ae8e2eb05a'	System	26 Sep 2020 01:52:27
User entered 'None (0)'	System	26 Sep 2020 01:52:27

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:52:15', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '0e91c6f7-c370-473b-aec2-06ae8e2eb05a'	System	26 Sep 2020 01:52:27
User entered 'None (0)'	System	26 Sep 2020 01:52:27

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:52:22', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '0e91c6f7-c370-473b-aec2-06ae8e2eb05a'	System	26 Sep 2020 01:52:27
User entered 'No (N)'	System	26 Sep 2020 01:52:27



US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-25T21:52:24', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '0e91c6f7-c370-473b-aec2-06ae8e2eb05a'	System	26 Sep 2020 01:52:27
User entered '25 Sep 2020 21:52'	System	26 Sep 2020 01:52:27

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 4'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:06:03', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '821e4b6d-99a1-4b22-ac43-5b76d9d6ef4a'	System	27 Sep 2020 03:06:37
User entered 'None (0)'	System	27 Sep 2020 03:06:37

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:06:06', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '821e4b6d-99a1-4b22-ac43-5b76d9d6ef4a'	System	27 Sep 2020 03:06:37
User entered 'None (0)'	System	27 Sep 2020 03:06:37

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:06:09', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '821e4b6d-99a1-4b22-ac43-5b76d9d6ef4a'	System	27 Sep 2020 03:06:37
User entered 'None (0)'	System	27 Sep 2020 03:06:37

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:06:13', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '821e4b6d-99a1-4b22-ac43-5b76d9d6ef4a'	System	27 Sep 2020 03:06:37
User entered 'None (0)'	System	27 Sep 2020 03:06:37



US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:06:18', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '821e4b6d-99a1-4b22-ac43-5b76d9d6ef4a'	System	27 Sep 2020 03:06:37
User entered 'None (0)'	System	27 Sep 2020 03:06:37

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:06:25', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '821e4b6d-99a1-4b22-ac43-5b76d9d6ef4a'	System	27 Sep 2020 03:06:37
User entered 'None (0)'	System	27 Sep 2020 03:06:37

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:06:31', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '821e4b6d-99a1-4b22-ac43-5b76d9d6ef4a'	System	27 Sep 2020 03:06:37
User entered 'No (N)'	System	27 Sep 2020 03:06:37

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-26T23:06:34', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '821e4b6d-99a1-4b22-ac43-5b76d9d6ef4a'	System	27 Sep 2020 03:06:37
User entered '26 Sep 2020 23:06'	System	27 Sep 2020 03:06:37

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 5'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:02:30', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8f909298-b2d5-4f45-a73f-a5b46178e580'	System	28 Sep 2020 00:02:56
User entered 'None (0)'	System	28 Sep 2020 00:02:56



US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:02:34', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8f909298-b2d5-4f45-a73f-a5b46178e580'	System	28 Sep 2020 00:02:56
User entered 'None (0)'	System	28 Sep 2020 00:02:56

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:02:37', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8f909298-b2d5-4f45-a73f-a5b46178e580'	System	28 Sep 2020 00:02:56
User entered 'None (0)'	System	28 Sep 2020 00:02:56

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:02:40', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8f909298-b2d5-4f45-a73f-a5b46178e580'	System	28 Sep 2020 00:02:56
User entered 'None (0)'	System	28 Sep 2020 00:02:56

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:02:44', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8f909298-b2d5-4f45-a73f-a5b46178e580'	System	28 Sep 2020 00:02:56
User entered 'None (0)'	System	28 Sep 2020 00:02:56

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:02:47', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8f909298-b2d5-4f45-a73f-a5b46178e580'	System	28 Sep 2020 00:02:56
User entered 'None (0)'	System	28 Sep 2020 00:02:56

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:02:51', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8f909298-b2d5-4f45-a73f-a5b46178e580'	System	28 Sep 2020 00:02:56
User entered 'No (N)'	System	28 Sep 2020 00:02:56

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-27T20:02:54', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '8f909298-b2d5-4f45-a73f-a5b46178e580'	System	28 Sep 2020 00:02:56
User entered '27 Sep 2020 20:02'	System	28 Sep 2020 00:02:56

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 16:57:19



US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 6'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

**US3222311**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:07:28**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25



US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

**US3222311**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:07:28**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	23 Sep 2020 16:57:19
User entered 'Day 7'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T17:00:36', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '5fab714d-6f0f-4e32-8bbf-46a8621d5c47'	System	29 Sep 2020 21:01:38
User entered 'None (0)'	System	29 Sep 2020 21:01:38

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T17:00:58', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '5fab714d-6f0f-4e32-8bbf-46a8621d5c47'	System	29 Sep 2020 21:01:38
User entered 'None (0)'	System	29 Sep 2020 21:01:38

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T17:01:01', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '5fab714d-6f0f-4e32-8bbf-46a8621d5c47'	System	29 Sep 2020 21:01:38
User entered 'None (0)'	System	29 Sep 2020 21:01:38



US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T17:01:05', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '5fab714d-6f0f-4e32-8bbf-46a8621d5c47'	System	29 Sep 2020 21:01:38
User entered 'None (0)'	System	29 Sep 2020 21:01:38

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T17:01:10', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '5fab714d-6f0f-4e32-8bbf-46a8621d5c47'	System	29 Sep 2020 21:01:38
User entered 'None (0)'	System	29 Sep 2020 21:01:38

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T17:01:14', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '5fab714d-6f0f-4e32-8bbf-46a8621d5c47'	System	29 Sep 2020 21:01:38
User entered 'No interference with activity (1)'	System	29 Sep 2020 21:01:38

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T17:01:26', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '5fab714d-6f0f-4e32-8bbf-46a8621d5c47'	System	29 Sep 2020 21:01:38
User entered 'Yes (Y)'	System	29 Sep 2020 21:01:38

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-09-29T17:01:31', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '5fab714d-6f0f-4e32-8bbf-46a8621d5c47'	System	29 Sep 2020 21:01:38
User entered '29 Sep 2020 17:01'	System	29 Sep 2020 21:01:38

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 16:57:19

US3222311

Folder: Diary Dose 2 (1)

Form: Chills\_Day(8)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	29 Sep 2020 21:01:38
User entered 'Day 8'	System	29 Sep 2020 21:01:38



US3222311

Folder: Diary Dose 2 (1)

Form: Chills\_Day(8)

Generated On: 09 Jun 2021 16:07:28

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Chills\_Day(8)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 21:01:38

US3222311

Folder: Diary Dose 2 (1)

Form: Chills\_Day(8)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 21:01:38

US3222311

Folder: Diary Dose 2 (1)

Form: Chills\_Day(8)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Chills\_Day(9)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	29 Sep 2020 21:01:38
User entered 'Day 9'	System	29 Sep 2020 21:01:38

US3222311

Folder: Diary Dose 2 (1)

Form: Chills\_Day(9)

Generated On: 09 Jun 2021 16:07:28

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

**US3222311**

**Folder: Diary Dose 2 (1)**

**Form: Chills\_Day(9)**

**Generated On: 09 Jun 2021 16:07:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 21:01:38

US3222311

Folder: Diary Dose 2 (1)

Form: Chills\_Day(9)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 21:01:38



US3222311

Folder: Diary Dose 2 (1)

Form: Chills\_Day(9)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	29 Sep 2020 21:00:07
User entered 'Day 8'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

**US3222311**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 16:07:28**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	29 Sep 2020 21:00:07
User entered 'Day 9'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25



US3222311

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:07:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25

US3222311

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:07:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 21:00:07

US3222311

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:07:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 21:00:07

US3222311

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:23:32

US3222311

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	31 Oct 2020 17:24:23
User entered '30 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4)	31 Oct 2020 17:24:23
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
User entered '29 Sep 2020'	System	31 Oct 2020 17:23:32
	douglas winter (b) (4)	31 Oct 2020 17:23:32
	(b) (4)	

US3222311

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:23:32

US3222311

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:23:32

US3222311

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:27:39



US3222311

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'I'	System	31 Oct 2020 17:27:39

US3222311

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:27:58

US3222311

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '7 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:27:58

US3222311

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:27:58

US3222311

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:27:58

US3222311

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:28:04

**US3222311**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'I'	System	31 Oct 2020 17:28:04

US3222311

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:28:19



US3222311

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '14 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:28:19

US3222311

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:28:19

US3222311

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:28:19

US3222311

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:28:23

**US3222311**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'I'	System	31 Oct 2020 17:28:23

US3222311

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:28:35

US3222311

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '20 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:28:35

US3222311

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Clinic (Clinic)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:28:35



**US3222311**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:07:28**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'VISIT3'	System	31 Oct 2020 17:28:35

US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:03

US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:03

**US3222311**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:03

US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered empty.	System	31 Oct 2020 17:29:03

US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:03

US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:03

US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:03



US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:03

**US3222311**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered empty.	System	31 Oct 2020 17:29:03

US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:03

US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered empty.	System	31 Oct 2020 17:29:03

US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:03

**US3222311**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered empty.	System	31 Oct 2020 17:29:03

US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:03

US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered empty.	System	31 Oct 2020 17:29:03



US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26

US3222311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26

US3222311

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:31

US3222311

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:31

US3222311

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:53

US3222311

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '20 Oct 2020'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:53

US3222311

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered '12:40'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:53

**US3222311**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:07:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered '20 Oct 2020 12:40'	System	31 Oct 2020 17:29:53



US3222311

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:47:31
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 17:29:58

**US3222311**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered '1'	System	31 Oct 2020 17:29:58

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 64'	System	24 Aug 2020 19:13:39

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[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)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37
Data entry locked.	System	24 Aug 2020 19:13:39
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 19:13:39

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37
Data entry locked.	System	24 Aug 2020 19:13:39
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 19:13:39

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 71'	System	24 Aug 2020 19:13:39

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[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)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37



US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37



US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37



US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37
Data entry locked.	System	24 Aug 2020 19:13:39
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 19:13:39

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:53:37
Data entry locked.	System	24 Aug 2020 19:13:39
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 19:13:39

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered 'Day 78'	System	24 Aug 2020 19:13:39

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

[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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-11-09T14:08:04', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'deac631b-ece5-402e-9f39-6c3648ba1a65'	System	09 Nov 2020 19:08:21
User entered 'No (N)'	System	09 Nov 2020 19:08:21

US3222311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:07:28

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)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-11-09T14:08:12', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'deac631b-ece5-402e-9f39-6c3648ba1a65'	System	09 Nov 2020 19:08:21
User entered 'No (N)'	System	09 Nov 2020 19:08:21

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-11-09T14:08:18', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'deac631b-ece5-402e-9f39-6c3648ba1a65'	System	09 Nov 2020 19:08:21
User entered '09 Nov 2020 14:08:18'	System	09 Nov 2020 19:08:21

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 19:13:39

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:21:25
Data entry locked.	System	24 Aug 2020 19:13:39
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 19:13:39



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[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 (8f760a0508ead15a)', Time: '2020-11-29T20:20:38', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'b5955cb5-2cad-4fd9-ae9e-74d9657b8f2f'	System	30 Nov 2020 01:21:07
User entered 'No (N)'	System	30 Nov 2020 01:21:07

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[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 (8f760a0508ead15a)', Time: '2020-11-29T20:20:54', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'b5955cb5-2cad-4fd9-ae9e-74d9657b8f2f'	System	30 Nov 2020 01:21:07
User entered 'No (N)'	System	30 Nov 2020 01:21:07

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-11-29T20:21:04', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'b5955cb5-2cad-4fd9-ae9e-74d9657b8f2f'	System	30 Nov 2020 01:21:07
User entered '29 Nov 2020 20:21:04'	System	30 Nov 2020 01:21:07

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[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 (8f760a0508ead15a)', Time: '2020-12-20T13:03:23', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '389b15ae-753a-4afd-95ff-ea0483b8eeea'	System	20 Dec 2020 18:04:07
User entered 'Yes (Y)'	System	20 Dec 2020 18:04:07

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 (8f760a0508ead15a)', Time: '2020-12-20T13:03:27', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '389b15ae-753a-4afd-95ff-ea0483b8eeea'	System	20 Dec 2020 18:04:07
User entered 'No (N)'	System	20 Dec 2020 18:04:07

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-12-20T13:03:35', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '389b15ae-753a-4afd-95ff-ea0483b8eeea'	System	20 Dec 2020 18:04:07
User entered 'No (N)'	System	20 Dec 2020 18:04:07

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-12-20T13:03:43', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '389b15ae-753a-4afd-95ff-ea0483b8eeea'	System	20 Dec 2020 18:04:07
User entered 'Yes (Y)'	System	20 Dec 2020 18:04:07

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-12-20T13:03:54', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '389b15ae-753a-4afd-95ff-ea0483b8eeea'	System	20 Dec 2020 18:04:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 18:04:07

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2020-12-20T13:03:59', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '389b15ae-753a-4afd-95ff-ea0483b8eeea' User entered '20 Dec 2020 13:03:59'	System	20 Dec 2020 18:04:07
	System	20 Dec 2020 18:04:07

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[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 (8f760a0508ead15a)', Time: '2021-01-24T13:27:52', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '2008db8f-e685-4714-87df-3cbc61f00a0a'	System	24 Jan 2021 18:28:03
User entered 'No (N)'	System	24 Jan 2021 18:28:03

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 (8f760a0508ead15a)', Time: '2021-01-24T13:27:57', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '2008db8f-e685-4714-87df-3cbc61f00a0a'	System	24 Jan 2021 18:28:03
User entered 'No (N)'	System	24 Jan 2021 18:28:03

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2021-01-24T13:28:00', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '2008db8f-e685-4714-87df-3cbc61f00a0a'	System	24 Jan 2021 18:28:03
User entered '24 Jan 2021 13:28:00'	System	24 Jan 2021 18:28:03



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[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 (8f760a0508ead15a)', Time: '2021-02-17T14:11:21', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f8209388-5f66-4b86-bfbd-b1f18bd526e5'	System	17 Feb 2021 19:11:39
User entered 'No (N)'	System	17 Feb 2021 19:11:39

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

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 (8f760a0508ead15a)', Time: '2021-02-17T14:11:32', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f8209388-5f66-4b86-bfbd-b1f18bd526e5'	System	17 Feb 2021 19:11:39
User entered 'No (N)'	System	17 Feb 2021 19:11:39

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2021-02-17T14:11:36', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'f8209388-5f66-4b86-bfbd-b1f18bd526e5' User entered '17 Feb 2021 14:11:36'	System	17 Feb 2021 19:11:39
	System	17 Feb 2021 19:11:39

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[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 (8f760a0508ead15a)', Time: '2021-03-24T10:43:57-04:00', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '27701cf6-13c6-4d74-87aa-e10cdfd219cc'	System	24 Mar 2021 14:44:06
User entered 'No (N)'	System	24 Mar 2021 14:44:06

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[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 (8f760a0508ead15a)', Time: '2021-03-24T10:44:00-04:00', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '27701cf6-13c6-4d74-87aa-e10cdfd219cc'	System	24 Mar 2021 14:44:06
User entered 'No (N)'	System	24 Mar 2021 14:44:06



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2021-03-24T10:44:03-04:00', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: '27701cf6-13c6-4d74-87aa-e10cdfd219cc'	System	24 Mar 2021 14:44:06
User entered '24 Mar 2021 10:44:03'	System	24 Mar 2021 14:44:06

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:53:37



**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:53:37

**US3222311**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:07:28**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:37
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:53:37

US3222311

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:07:28**

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)	25 Apr 2021 06:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2021-03-24T10:44:40-04:00', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7d8f24a-d6c8-4ac0-bbb1-8da2bdfcaf6b'	System	24 Mar 2021 14:44:50
User entered 'No (N)'	System	24 Mar 2021 14:44:50

**US3222311**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:32:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8f760a0508ead15a)', Time: '2021-03-24T10:44:47-04:00', User OID: 'PatientReportedOutcome (US3222311)', ODM File OID: 'e7d8f24a-d6c8-4ac0-bbb1-8da2bdfcaf6b' User entered '24 Mar 2021 10:44:47'	System	24 Mar 2021 14:44:50
	System	24 Mar 2021 14:44:50

**US3222311**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:07:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Dec 2020 16:50:30

US3222311

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '17 Nov 2020'	Albert Garcia (b) (4)	07 Dec 2020 16:50:30



US3222311

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	07 Dec 2020 16:50:30

US3222311

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	07 Dec 2020 16:50:30

US3222311

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Dec 2020 16:50:40

**US3222311**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 21:38:26
User entered 'I'	System	07 Dec 2020 16:50:40

US3222311

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:33:07
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	heather jackson (b) (4)	23 Dec 2020 14:42:38

US3222311

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:33:07
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '21 Dec 2020'	heather jackson (b) (4)	23 Dec 2020 14:42:38

US3222311

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:33:07
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Contact Made (CONTACT MADE)'	heather jackson (b) (4)	23 Dec 2020 14:42:38

US3222311

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:33:07
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	heather jackson (b) (4)	23 Dec 2020 14:42:38



US3222311

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:33:07
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	heather jackson (b) (4)	23 Dec 2020 14:42:42

**US3222311**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:33:07
User entered 'I'	System	23 Dec 2020 14:42:42

US3222311

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:33:07
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Feb 2021 14:01:57

US3222311

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:33:07
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '20 Jan 2021'	(b) (4) gail lavine (b) (4) (b) (4)	02 Feb 2021 14:01:57

US3222311

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:33:07
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Feb 2021 14:01:57

US3222311

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:33:07
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Feb 2021 14:01:57

US3222311

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:33:07
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Feb 2021 14:02:08

US3222311

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:33:07
User entered 'I'	System	02 Feb 2021 14:02:08



**US3222311**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:07:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:52:13
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:04:46

US3222311

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:52:13
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:04:46

**US3222311**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:07:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:52:13
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:04:46

US3222311

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:52:13
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
User closed query 'Per DM CLR: Comment = ON ANTIBIOTIC BEGIN OF FEB. Review if this medication should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Apr 2021 13:26:54
User closed query 'Per DM CLR: Comment = PT HAD BASIL CEL REMVD. Review if this procedure should also be captured on Concomitant Procedure page. If yes, please update Concomitant procedure page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 13:26:51
Query 'Per DM CLR: Comment = ON ANTIBIOTIC BEGIN OF FEB. Review if this medication should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' answered with 'ADDED TO CONMED PAGE, IN CRF AND SOURCE' (Site from DM).	douglas winter (b) (4) (b) (4)	24 Apr 2021 13:31:57
Query 'Per DM CLR: Comment = PT HAD BASIL CEL REMVD. Review if this procedure should also be captured on Concomitant Procedure page. If yes, please update Concomitant procedure page as appropriate. ' answered with 'ADDED TO CONMED PAGE, CONCOMITANT PROCEDURE PAGE IN CRF AND SOURCE' (Site from DM).	douglas winter (b) (4) (b) (4)	24 Apr 2021 13:31:22
Signature has been broken.	douglas winter (b) (4) (b) (4)	24 Apr 2021 12:57:40
User entered empty; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	24 Apr 2021 12:57:40
User opened query 'Per DM CLR: Comment = ON ANTIBIOTIC BEGIN OF FEB. Review if this medication should also be captured on Concomitant Medication page. If yes, please update Concomitant medication page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:16:27

US3222311

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Comment = PT HAD BASIL CEL REMVD. Review if this procedure should also be captured on Concomitant Procedure page. If yes, please update Concomitant procedure page as appropriate. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	01 Mar 2021 10:15:28
	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
User entered 'Spoke w/Subject's husband/ He stated that sub dnt have a cell phone because she has dementia and that he had not had any covid reactions. pt had basil cel remvd & on antibiotic begin of Feb'	(b) (4), (b) (6)	18 Feb 2021 17:04:46

US3222311

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:33:07
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:05:09

US3222311

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 11:33:07
User entered 'I'	System	18 Feb 2021 17:05:09

US3222311

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:08



US3222311

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:08

US3222311

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:08

**US3222311**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:07:28**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Mar 2021 18:17:08

US3222311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:12

US3222311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:12

US3222311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:12

**US3222311**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:17:12

US3222311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:12



US3222311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:12

US3222311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:12

US3222311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:12

**US3222311**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:17:12

US3222311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:12

**US3222311**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:17:12

US3222311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:12

**US3222311**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:17:12



US3222311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:12

US3222311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:17:12

US3222311

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:15

US3222311

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:15

US3222311

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:24

US3222311

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:24

US3222311

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '12:15'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:24

**US3222311**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:07:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 12:15'	System	30 Mar 2021 18:17:24



US3222311

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:28

**US3222311**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 18:17:28

US3222311

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 16:30:54

US3222311

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered '20 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 16:30:54

US3222311

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:54

US3222311

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:30:54

US3222311

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 16:30:59

**US3222311**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 16:30:59



US3222311

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

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:48:55

**US3222311**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:07:28**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '28 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:48:55

US3222311

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

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[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 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Clinic (Clinic)'	Diana Toney (b) (4)	28 Jan 2021 20:48:55

**US3222311**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:07:28**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 20:48:55

US3222311

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

Form: Unblinding

Generated On: 09 Jun 2021 16:07:28

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '28 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:49:20

**US3222311**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:07:28**

[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 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:50:22
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:31:42

US3222311

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

Form: Unblinding

Generated On: 09 Jun 2021 16:07:28

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:49:20

US3222311

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

Form: Unblinding

Generated On: 09 Jun 2021 16:07:28

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Apr 2021 15:03:25
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 12:50:30
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	22 Apr 2021 12:50:22
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 06:52:49
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:31:42



US3222311

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

Form: Unblinding

Generated On: 09 Jun 2021 16:07:28

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '28 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:49:20

US3222311

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

Form: Unblinding

Generated On: 09 Jun 2021 16:07:28

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Placebo (Placebo)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:49:20

US3222311

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

Form: Unblinding

Generated On: 09 Jun 2021 16:07:28

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Placebo (Placebo)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:49:20

US3222311

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

Form: Unblinding

Generated On: 09 Jun 2021 16:07:28

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Placebo (Placebo)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:49:20

US3222311

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

Form: Unblinding

Generated On: 09 Jun 2021 16:07:28

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:49:20

**US3222311**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:07:28**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '1'	System	28 Jan 2021 20:49:20

**US3222311**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:07:28**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'I'	System	28 Jan 2021 20:49:20

US3222311

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '172.7' cm	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59



US3222311

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '74.8' kg	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '25.07939'	System	28 Jan 2021 20:51:59
DataPoint set to visible.	System	28 Jan 2021 20:49:20

US3222311

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '172.7' cm	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '74.8' kg	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '25.07939'	System	28 Jan 2021 20:51:59
DataPoint set to visible.	System	28 Jan 2021 20:49:20

US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User accepted default value 'Pre-Dose (PREDOSE)'	Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '28 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59



US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '12:24'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '28 Jan 2021 12:24'	System	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '36.7' C	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Oral (Oral)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '66'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

**US3222311**

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

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'bpm'	System	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '16'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59



US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'breaths/min'	System	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '124'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'mmHg'	System	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '65'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'mmHg'	System	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '172.7' cm	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '74.8' kg	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:07:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '25.07939'	System	28 Jan 2021 20:51:59
DataPoint set to visible.	System	28 Jan 2021 20:49:20



US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User accepted default value 'Post-Dose (POSTDOSE)'	Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '28 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

**US3222311**

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

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '13:35'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '28 Jan 2021 13:35'	System	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '36.5' C	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Oral (Oral)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59



US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '65'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'bpm'	System	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '16'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'breaths/min'	System	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '122'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'mmHg'	System	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '63'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:51:59

US3222311

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'mmHg'	System	28 Jan 2021 20:51:59



US3222311

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:52:12

US3222311

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '28 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:52:12

US3222311

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

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:52:48

US3222311

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

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:52:48

US3222311

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

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

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 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:52:48

US3222311

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

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'mRNA-1273'	System	28 Jan 2021 20:52:48
DataPoint set to visible.	System	28 Jan 2021 20:49:20

US3222311

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

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '28 Jan 2021'	Diana Toney (b) (4)	28 Jan 2021 20:52:48

US3222311

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

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '13:04'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:52:48



US3222311

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

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '28 Jan 2021 13:04'	System	28 Jan 2021 20:52:48

US3222311

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

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:52:48

US3222311

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

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'ONCE'	System	28 Jan 2021 20:52:48

US3222311

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

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'INTRAMUSCULAR'	System	28 Jan 2021 20:52:48

US3222311

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:53:15

US3222311

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '28 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:53:15

**US3222311**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:07:28**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '12:45'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:53:15

**US3222311**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:07:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '28 Jan 2021 12:45'	System	28 Jan 2021 20:53:15



US3222311

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:07:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:53:31

**US3222311**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:07:28**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '28 Jan 2021'	Diana Toney (b) (4)	28 Jan 2021 20:53:31

**US3222311**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:07:28**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '12:47'	Diana Toney (b) (4)	28 Jan 2021 20:53:31

**US3222311**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:07:28**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered '28 Jan 2021 12:47'	System	28 Jan 2021 20:53:31

US3222311

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

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	28 Jan 2021 20:53:41

**US3222311**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:48:35
User entered 'I'	System	28 Jan 2021 20:53:41

US3222311

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:55:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
Signature has been broken. (WR# 5303595)	System	12 Apr 2021 18:13:34
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:43:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 21:46:20

US3222311

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:55:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
Signature has been broken. (WR# 5303595)	System	12 Apr 2021 18:13:34
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:43:14
	(b) (4)	
User entered '04 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 21:46:20



US3222311

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:55:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
Signature has been broken. (WR# 5303595)	System	12 Apr 2021 18:13:34
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:43:14
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Feb 2021 21:46:20

US3222311

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:55:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
Signature has been broken. (WR# 5303595)	System	12 Apr 2021 18:13:34
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:43:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:46:20

US3222311

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:55:03
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
Signature has been broken. (WR# 5303595)	System	12 Apr 2021 18:13:34
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:43:14
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 21:46:25

US3222311

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:55:03
User entered 'I'	System	25 Feb 2021 21:46:25

**US3222311**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:55:03
User entered 'I'	System	25 Feb 2021 21:46:25
DataPoint set to visible.	System	25 Feb 2021 21:46:25

US3222311

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:43:14
User entered 'Yes (Y)'	Vicki Miller (b) (4)	25 Feb 2021 21:46:41
	(b) (4)	
	(b) (4), (b) (6)	

US3222311

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:43:14
User entered '25 Feb 2021'	Vicki Miller (b) (4)	25 Feb 2021 21:46:41
	(b) (4)	
	(b) (4), (b) (6)	

US3222311

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:43:14
User entered 'Clinic (Clinic)'	Vicki Miller (b) (4)	25 Feb 2021 21:46:41
	(b) (4)	
	(b) (4), (b) (6)	



US3222311

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered 'OLD29'	System	25 Feb 2021 21:46:41

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

**US3222311**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '12:08'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered '25 Feb 2021 12:08'	System	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '37' C	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03



US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '65'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered 'bpm'	System	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '18'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered 'breaths/min'	System	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '114'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

**US3222311**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered 'mmHg'	System	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '66'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03



US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered 'mmHg'	System	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

**US3222311**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:07:28**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '13:39'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered '25 Feb 2021 13:39'	System	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03



US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '67'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered 'bpm'	System	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '18'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered 'breaths/min'	System	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '106'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:48:03

**US3222311**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered 'mmHg'	System	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:32:26
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per PI Dr Rankin' (Site from System).	(b) (4), (b) (6)	08 Apr 2021 17:48:22
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		25 Feb 2021 21:48:03
User entered '41'	(b) (4), (b) (6)	25 Feb 2021 21:48:03



**US3222311**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered 'mmHg'	System	25 Feb 2021 21:48:03

US3222311

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:43:14
User entered 'Yes (Y)'	Vicki Miller (b) (4)	25 Feb 2021 21:48:25
	(b) (4)	
	(b) (4), (b) (6)	

US3222311

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:43:14
User entered '25 Feb 2021'	Vicki Miller (b) (4)	25 Feb 2021 21:48:25
	(b) (4)	
	(b) (4), (b) (6)	

US3222311

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:43:14
User entered 'Yes (Y)'	Vicki Miller (b) (4)	25 Feb 2021 21:48:40
	(b) (4)	
	(b) (4), (b) (6)	

US3222311

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:43:14
User entered empty.	Vicki Miller (b) (4)	25 Feb 2021 21:48:40
	(b) (4)	
	(b) (4), (b) (6)	

US3222311

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

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)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	12 Apr 2021 18:13:34
	Vicki Miller (b) (4)	26 Feb 2021 21:43:14
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 21:48:40

US3222311

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered 'mRNA-1273'	System	25 Feb 2021 21:48:40
DataPoint set to visible.	System	25 Feb 2021 21:46:25

US3222311

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:43:14
User entered '25 Feb 2021'	Vicki Miller (b) (4)	25 Feb 2021 21:48:40
	(b) (4)	
	(b) (4), (b) (6)	



US3222311

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:43:14
User entered '13:09'	Vicki Miller (b) (4)	25 Feb 2021 21:48:40
	(b) (4)	
	(b) (4), (b) (6)	

**US3222311**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:07:28**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered '25 Feb 2021 13:09'	System	25 Feb 2021 21:48:40

US3222311

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:43:14
User entered 'Left Arm (LEFT ARM)'	Vicki Miller (b) (4)	25 Feb 2021 21:48:40
	(b) (4)	
	(b) (4), (b) (6)	

US3222311

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered 'ONCE'	System	25 Feb 2021 21:48:40

US3222311

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:07:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 21:48:40

US3222311

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:07:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	26 Feb 2021 21:43:14
User entered 'Yes (Y)'	Vicki Miller (b) (4)	25 Feb 2021 21:48:45
	(b) (4)	
	(b) (4), (b) (6)	

**US3222311**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:49
User entered 'I'	System	25 Feb 2021 21:48:45

**US3222311**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:07:28**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:21:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:18:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:12:38



**US3222311**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:07:28**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:21:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:18:18
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:12:38

**US3222311**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:07:28**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:21:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:18:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:12:38

US3222311

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:07:28

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:21:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:18:18
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:12:38

**US3222311**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:21:35
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:18:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:12:46

**US3222311**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:07:28**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:21:35
User entered 'I'	System	04 Mar 2021 17:12:46

**US3222311**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:07:28**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:40

**US3222311**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:07:28**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:40

US3222311

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:07:28

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:40



**US3222311**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:07:28**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 18:17:40

US3222311

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:45

US3222311

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:45

US3222311

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:45

**US3222311**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:17:45

US3222311

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:45

US3222311

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:45

US3222311

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:45



US3222311

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:45

**US3222311**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:17:45

US3222311

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:45

**US3222311**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:17:45

US3222311

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:45

**US3222311**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:17:45

US3222311

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:07:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:45

**US3222311**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:07:28**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 18:17:45



US3222311

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:49

US3222311

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:07:28

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:17:49

US3222311

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:18:00

US3222311

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:18:00

US3222311

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:07:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '12:15'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:18:00

**US3222311**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:07:28**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 12:15'	System	30 Mar 2021 18:18:00

US3222311

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:07:28

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:12
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:01:28
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:06:24

US3222311

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:01:56
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:31
User entered	System	12 Oct 2020 14:57:17
'USA-US104-2020-mRNA-1273-P301000012'		
User entered 'New'	(b) (4), (b) (6)	12 Oct 2020 14:57:17



US3222311

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:01:58
User closed query 'PV Query: Please clarify event term as narrative reads "Patient had tingling on a side went to the hospital. Ruled out stroke and confirmed UTI". Please report the final diagnosis/etiology of symptoms and update event term accordingly. ' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 19:35:55
Query 'PV Query: Please clarify event term as narrative reads "Patient had tingling on a side went to the hospital. Ruled out stroke and confirmed UTI". Please report the final diagnosis/etiology of symptoms and update event term accordingly. ' answered with 'URINARY TRACT INFECTION' (Site from Safety).	douglas winter (b) (4)	31 Oct 2020 15:51:57
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\23.0.	Coder Import (b) (4)	31 Oct 2020 15:39:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	31 Oct 2020 15:39:20
Data point term sent to Coder	System	31 Oct 2020 15:38:13
Coding entries removed.	douglas winter (b) (4)	31 Oct 2020 15:37:55
User entered 'URINARY TRACT INFECTION' reason for change: Data Entry Error	(b) (4)	31 Oct 2020 15:37:55
User opened query 'PV Query: Please clarify event term as narrative reads "Patient had tingling on a side went to the hospital. Ruled out stroke and confirmed UTI". Please report the final diagnosis/etiology of symptoms and update event term accordingly. ' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 18:13:21
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\23.0.	Coder Import (b) (4)	09 Oct 2020 21:21:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. Data point term sent to Coder	Coder Import (b) (4)	09 Oct 2020 21:21:35
User entered 'STROKE LIKE SYMPTOMS'	System	09 Oct 2020 21:12:57
	douglas winter (b) (4)	09 Oct 2020 21:12:00
	(b) (4)	

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:02:01
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:02:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

US3222311

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:02:10
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

US3222311

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User closed query 'PV Query: Hospitalization date was reported as one day prior to event start date. Please consider updating event start date or report additional events for subject's initial hospitalization.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:12:17
Query 'PV Query: Hospitalization date was reported as one day prior to event start date. Please consider updating event start date or report additional events for subject's initial hospitalization.' answered with 'UPDATED' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:38:06
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:37:25
User entered '28 Sep 2020' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:37:25
User opened query 'PV Query: Hospitalization date was reported as one day prior to event start date. Please consider updating event start date or report additional events for subject's initial hospitalization.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 14:50:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:02:13
User entered '29 Sep 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

US3222311

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:02:18
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:07:28**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 21:12:00



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:02:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

US3222311

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:02:24
User entered '30 Sep 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

US3222311

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:02:26
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:07:28**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 21:12:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:02:31
User entered 'Grade 4 (Grade 4)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

US3222311

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4)	24 Apr 2021 13:22:50
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	24 Apr 2021 13:22:50
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	24 Apr 2021 13:22:50
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	24 Apr 2021 13:22:50
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4)	24 Apr 2021 13:21:13
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	24 Apr 2021 13:21:13
DataPoint Un-verified.	douglas winter (b) (4)	24 Apr 2021 13:21:13
Signature has been broken.	(b) (4)	24 Apr 2021 13:21:13
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	24 Apr 2021 13:21:13
User signature succeeded.	(b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:02:33
User entered 'Yes (Y)'	douglas winter (b) (4)	09 Oct 2020 21:12:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:02:35
User entered '0'	douglas winter (b) (4)	09 Oct 2020 21:12:00
	(b) (4)	

US3222311

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:02:37
User entered '0'	douglas winter (b) (4)	09 Oct 2020 21:12:00
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:02:40
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 19:36:39
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with '24 HOUR OVERNIGHT HOSPITALIZATION' (Site from Safety).	douglas winter (b) (4) (b) (4)	31 Oct 2020 15:24:44
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 18:17:21
User entered 'I'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:02:44
User entered '28 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	31 Oct 2020 15:37:55
User entered '29 Sep 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:08:58
User entered '30 Sep 2020'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:24
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:27
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:09:29
User entered '0'	douglas winter (b) (4)	09 Oct 2020 21:12:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:09:35
User entered '0'	douglas winter (b) (4)	09 Oct 2020 21:12:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:09:47
User entered '0'	douglas winter (b) (4)	09 Oct 2020 21:12:00
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:09:55
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4)	09 Oct 2020 21:12:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User closed query 'PV Query: As the last dose of mRNA-1273 vs Placebo was given on 23-Sep-2020, please update the action taken with mRNA-1273 vs Placebo from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:01:58
Query 'PV Query: As the last dose of mRNA-1273 vs Placebo was given on 23-Sep-2020, please update the action taken with mRNA-1273 vs Placebo from none to not applicable.' answered with 'corrected' (Site from Safety).	gail lavine (b) (4) (b) (4)	02 Dec 2020 12:52:20
DataPoint Un-verified.	gail lavine (b) (4) (b) (4)	02 Dec 2020 12:51:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	02 Dec 2020 12:51:53
User opened query 'PV Query: As the last dose of mRNA-1273 vs Placebo was given on 23-Sep-2020, please update the action taken with mRNA-1273 vs Placebo from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:46:35
User closed query 'PV Query: As the last dose of mRNA-1273 vs Placebo was given on 23-Sep-2020, please update the action taken with mRNA-1273 vs Placebo from none to not applicable. If study drug has been given since 23-Sep-2020, please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:11:48
Query 'PV Query: As the last dose of mRNA-1273 vs Placebo was given on 23-Sep-2020, please update the action taken with mRNA-1273 vs Placebo from none to not applicable. If study drug has been given since 23-Sep-2020, please update the EDC accordingly.' answered with '23SEP2020 WAS THE 2ND AND FINAL VACCINE.' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:39:03
User opened query 'PV Query: As the last dose of mRNA-1273 vs Placebo was given on 23-Sep-2020, please update the action taken with mRNA-1273 vs Placebo from none to not applicable. If study drug has been given since 23-Sep-2020, please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 14:48:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:11:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:11:05
User entered '0'	douglas winter (b) (4)	09 Oct 2020 21:12:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:38:06
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'CONMEDS HAVE BEEN ADDED. PLEASE REVIEW. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:39:38
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:14:20
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 02:16:47
User entered 'I'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:14:25
User entered '0'	douglas winter (b) (4)	09 Oct 2020 21:12:00
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:14:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:14:31
User entered empty.	douglas winter (b) (4) (b) (4)	09 Oct 2020 21:12:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User closed query 'Per DM CLR: SAE Narrative = SUBJECT HAD FALLEN. Please review and confirm if this should be recorded as a separate Adverse Event. If yes, please record the medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 13:10:18
Query 'Per DM CLR: SAE Narrative = SUBJECT HAD FALLEN. Please review and confirm if this should be recorded as a separate Adverse Event. If yes, please record the medical condition in the AE eCRF as appropriate. ' answered with 'Fall added to AE's' (Site from DM).	gail lavine (b) (4) (b) (4)	02 Dec 2020 13:15:27
User opened query 'Per DM CLR: SAE Narrative = SUBJECT HAD FALLEN. Please review and confirm if this should be recorded as a separate Adverse Event. If yes, please record the medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 00:46:16
User closed query 'PV Query: please provide results for bilateral carotid ultrasound' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:11:59
Query 'PV Query: please provide results for bilateral carotid ultrasound' answered with 'THESE RESULTS ARE NOT PRESENT IN THE DISCHARGE SUMMARY, BUT ARE ASSUMED TO BE OF NO CS SINCE THEY ARE NOT NOTED ELSEWHERE. ' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:46:45
User opened query 'PV Query: please provide results for bilateral carotid ultrasound' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 14:49:46
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:14:55
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 19:36:57

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 19:36:54
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (Ie. urinalysis, urine culture, imaging studies etc.). Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 19:36:52
User closed query 'PV Query: It was reported that stroke was ruled out. Please provide results of the imaging studies, laboratory results and clinical evaluations that ruled out stroke. ' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 19:36:49
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 19:36:47
User entered 'FOUND OUT TODAY @ 11:21 AM THAT THE SUBJECT HAD FALLEN AND STARTED TO EXPERIENCE TINGLING TO THE RIGHT SIDE AND WAS ADMITTED TO THE HOSPITAL. RULED OUT STROKE AND CONFIRMED UTI. SHE HAS A HISTORY OF CVA WITH RESIDUAL DEFICITS.' reason for change: Data Entry Error	douglas winter (b) (4)	31 Oct 2020 16:08:32
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'NOT DONE' (Site from Safety).	douglas winter (b) (4)	31 Oct 2020 15:51:35
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' answered with 'HISTORY OF CVA WITH RESIDUAL DEFICITS, HISTORY OF DEMENTIA, METABOLIC ENCEPHALOPATHY, TIA.' (Site from Safety).	douglas winter (b) (4)	31 Oct 2020 15:50:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'CEFDINIR 300 MG BID ORAL FOR 10 DAYS CHANGED DULOXETINE DOSE FROM 60 MG TO 40 MG QD' (Site from Safety).	douglas winter (b) (4) (b) (4)	31 Oct 2020 15:46:38
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (Ie. urinalysis, urine culture, imaging studies etc.). Please include units and reference ranges if applicable. ' answered with 'CT/HEAD NEGATIVE FOR NEW CVA, MR BRAIN NEGATIVE, US CAROTID DUPLEX BIL. UA WBC CLUMPS, URINE CULTURE INDICATED BLADDER INFECTION.' (Site from Safety).	douglas winter (b) (4) (b) (4)	31 Oct 2020 15:38:35
Query 'PV Query: It was reported that stroke was ruled out. Please provide results of the imaging studies, laboratory results and clinical evaluations that ruled out stroke. ' answered with 'CT/HEAD NEGATIVE FOR NEW CVA, MR BRAIN NEGATIVE, US CAROTID DUPLEX BIL. UA WBC CLUMPS, URINE CULTURE INDICATED BLADDER INFECTION.' (Site from Safety).	douglas winter (b) (4) (b) (4)	31 Oct 2020 15:38:27
User entered 'FOUND OUT TODAY @ 11:21 AM THAT THE SUBJECT HAD EXPERIENCED TINGLING TO THE RIGHT SIDE AND WAS ADMITTED TO THE HOSPITAL. RULED OUT STROKE AND CONFIRMED UTI.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	31 Oct 2020 15:37:55
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 18:15:42

US3222311

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:07:28

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 18:15:21
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (Ie. urinalysis, urine culture, imaging studies etc.). Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 18:15:09
User opened query 'PV Query: It was reported that stroke was ruled out. Please provide results of the imaging studies, laboratory results and clinical evaluations that ruled out stroke. ' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 18:14:34
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 18:14:09
User entered 'FOUND OUT TODAY @ 11:21 AM THAT the SUBJECT HAD EXPERIENCED TINGLING TO the RIGHT SIDE AND WAS ADMITTED TO THE HOSPITAL. RULED OUT STROKE AND CONFIRMED UTI. REQUESTING RECORDS'	douglas winter (b) (4)	09 Oct 2020 21:12:00

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Apr 2021 13:22:50
User entered '0'	System	24 Apr 2021 13:21:13
User entered '1'	System	09 Oct 2020 21:12:00

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 21:12:00

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 21:12:00



**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:07:28**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 13:16:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 13:16:07
Data point term sent to Coder	System	02 Dec 2020 13:14:39
User entered 'Fall'	gail lavine (b) (4)	02 Dec 2020 13:14:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '30 Sep 2020'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:07:28**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User entered empty.	System	02 Dec 2020 13:14:03



**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '30 Sep 2020'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User entered empty.	System	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03



US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	02 Dec 2020 13:14:12
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	gail lavine (b) (4)	02 Dec 2020 13:14:12
User entered '0'	(b) (4)	
	System	02 Dec 2020 13:14:03
	gail lavine (b) (4)	02 Dec 2020 13:14:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

US3222311

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) gail lavine (b) (4) (b) (4)	02 Dec 2020 13:14:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:07:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User entered '0'	System	02 Dec 2020 13:14:03

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16
User entered 'I'	System	02 Dec 2020 13:14:03

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:16

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 12:52:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 12:52:52
Data point term sent to Coder	System	08 Dec 2020 12:52:25
User entered 'URINARY TRACT INFECTION'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	08 Dec 2020 12:52:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4)	08 Dec 2020 12:52:06



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4) (b) (4)	08 Dec 2020 12:52:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '4 Dec 2020'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	08 Dec 2020 12:52:18
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	08 Dec 2020 12:52:18
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	08 Dec 2020 12:52:06
User entered '00:00'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:07:28**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User entered empty.	System	08 Dec 2020 12:52:18
User entered '4 Dec 2020 00:00'	System	08 Dec 2020 12:52:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	12 Feb 2021 12:24:25
User entered 'Yes (Y)'	Alicia Cevera (b) (4)	08 Dec 2020 12:52:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	12 Feb 2021 12:24:40
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	12 Feb 2021 12:24:40
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	12 Feb 2021 12:24:25
User entered '15 Dec 2020' reason for change: Data Entry Error	Alicia Cevera (b) (4)	12 Feb 2021 12:24:25
User entered empty.	(b) (4)	
	Albert Garcia (b) (4)	08 Dec 2020 12:52:06
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:07:28**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:07:28**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User entered empty.	System	08 Dec 2020 12:52:06



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

US3222311

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

US3222311

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	Albert Garcia (b) (4)	08 Dec 2020 12:52:06



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Albert Garcia (b) (4)	08 Dec 2020 12:52:06

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Not Related (NOT RELATED)'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Not Related (NOT RELATED)'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'None (NONE)'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:07:28**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'I'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Alicia Cevera (b) (4)	12 Feb 2021 12:24:40
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	
	Albert Garcia (b) (4)	08 Dec 2020 12:52:06
	(b) (4)	

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	08 Dec 2020 12:52:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:07:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User closed query 'Per DM CLR: RQ: Response noted, however, LEVAQUIN is still not recorded in the CM page. Please review and reconcile records as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 12:51:12
Query 'Per DM CLR: RQ: Response noted, however, LEVAQUIN is still not recorded in the CM page. Please review and reconcile records as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:53:41
User opened query 'Per DM CLR: RQ: Response noted, however, LEVAQUIN is still not recorded in the CM page. Please review and reconcile records as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 02:11:25
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User closed query 'Per DM CLR: Narrative indicates that the subject was given Levaquin 500 mg QD. However, there is no corresponding ConMed record that match the information. Please update to record the corresponding medication as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:47:40
Query 'Per DM CLR: Narrative indicates that the subject was given Levaquin 500 mg QD. However, there is no corresponding ConMed record that match the information. Please update to record the corresponding medication as appropriate. Otherwise, clarify.' answered with 'SOURCE UPDATED' (Site from DM).	Alicia Cevera (b) (4)	12 Feb 2021 12:23:53
User opened query 'Per DM CLR: Narrative indicates that the subject was given Levaquin 500 mg QD. However, there is no corresponding ConMed record that match the information. Please update to record the corresponding medication as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 10:40:06
User entered 'SUBJECT WAS DX WITH UTI ON 12/4 AND IS PROCEEDING WITH A 10 DAY COURSE OF LEVAQUIN 500 MG QD.'	Albert Garcia (b) (4)	08 Dec 2020 12:52:06

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User entered '0'	System	08 Dec 2020 12:52:06

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09
User entered '1'	System	08 Dec 2020 12:52:06

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:09



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	(b) (4)	
	Coder Import (b) (4)	12 Feb 2021 12:44:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 12:44:45
	(b) (4)	
Data point term sent to Coder	System	12 Feb 2021 12:43:49
User entered 'knee pain'	Alicia Cevera (b) (4)	12 Feb 2021 12:43:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '15 Dec 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User entered empty.	System	12 Feb 2021 12:43:37



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '15 Dec 2020'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:07:28**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User entered empty.	System	12 Feb 2021 12:43:37

US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	(b) (4) Alicia Cevera (b) (4)	12 Feb 2021 12:43:37

US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37



US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'None (NONE)'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 12:51:39
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'tramadol documented ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:01:23
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 02:12:05
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	20 Feb 2021 14:46:45
User entered 'I'	Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '0'	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37

US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alicia Cevera (b) (4)	12 Feb 2021 12:43:37

US3222311

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered empty.	(b) (4) Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:43:37



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:07:28

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'this ae is secondary to fall in Sep 2020. subject stated she has arthritis and that is what the pain is from.'	(b) (4) Alicia Cevera (b) (4)	12 Feb 2021 12:43:37

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User entered '0'	System	12 Feb 2021 12:43:37

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10
User entered '0'	System	12 Feb 2021 12:43:37

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:10

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:07:28**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Micrographic skin surgery, LLT: Mohs micrographic surgery - version MedDRA\\23.0.	Coder Import (b) (4)	24 Apr 2021 13:29:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Apr 2021 13:29:01
Data point term sent to Coder	System	24 Apr 2021 13:28:22
User entered 'MOHS SURGERY'	douglas winter (b) (4)	24 Apr 2021 13:28:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:28:18

US3222311

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:28:18



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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:07:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:28:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '02 Feb 2021'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User entered empty.	System	24 Apr 2021 13:28:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:28:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '02 Feb 2021'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:07:28**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User entered empty.	System	24 Apr 2021 13:28:18



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:28:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:28:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

US3222311

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

US3222311

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:28:18

US3222311

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:28:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18



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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

US3222311

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

US3222311

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

US3222311

Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

US3222311

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Not Related (NOT RELATED)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

US3222311

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:28:18

US3222311

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18



US3222311

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

US3222311

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'I'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

US3222311

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:28:18

US3222311

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:07:28

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

US3222311

Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'REMOVED BASAL CELL CARCINOMA FROM LEFT CHEAK.'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:28:18

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:07:28**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User entered '0'	System	24 Apr 2021 13:28:18

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:07:28**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18
User entered '1'	System	24 Apr 2021 13:28:18

**US3222311**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 16:07:28**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:39:18



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:07:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:12
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User closed query 'Per ETRTR: According to SAE "Stroke Like Symptoms" page, medication was dosed for SAE. Please add Medication dosing details for SAE "Stroke Like Symptoms " within ConMeds page, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:15:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:15:45
Query 'Per ETRTR: According to SAE "Stroke Like Symptoms" page, medication was dosed for SAE. Please add Medication dosing details for SAE "Stroke Like Symptoms " within ConMeds page, thanks.' answered with 'UPDATING MEDICATION PAGE' (Site from CRA).	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:09:43
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:09:19
User opened query 'Per ETRTR: According to SAE "Stroke Like Symptoms" page, medication was dosed for SAE. Please add Medication dosing details for SAE "Stroke Like Symptoms " within ConMeds page, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 00:56:05
User entered 'No (N)'	Amber Vasquez (b) (4) (b) (4)	10 Oct 2020 22:14:41

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 20:12:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 20:12:23
Data point term sent to Coder Coding entries removed.	System douglas winter (b) (4)	05 Nov 2020 19:57:02 05 Nov 2020 19:56:23
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:49:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 16:13:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 16:13:12
Data point term sent to Coder User entered 'ASPIRIN'	System douglas winter (b) (4)	31 Oct 2020 16:12:18 31 Oct 2020 16:12:01

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:49:54
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:12:01

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
DataPoint Un-verified.	douglas winter (b) (4)	05 Nov 2020 19:56:23
	(b) (4)	
User entered 'CARDIAC PROPHYLAXIS' reason for change: Data Entry Error	douglas winter (b) (4)	05 Nov 2020 19:56:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:49:56
User entered 'PROPHYLAXIS'	douglas winter (b) (4)	31 Oct 2020 16:12:01
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:49:58
User entered '81'	douglas winter (b) (4)	31 Oct 2020 16:12:01
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:50:39
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:12:01

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:07:28**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:50:46
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 16:50:44
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:50:42
User entered empty.	douglas winter (b) (4)	31 Oct 2020 16:12:01
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:50:48
User entered 'once daily (QD)'	douglas winter (b) (4)	31 Oct 2020 16:12:01
	(b) (4)	



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:50:51
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:12:01

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:51:01
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:12:01

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:07:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:51:04
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:12:01

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Per source, medication was started 01Jan06. Please verify and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:29:11
User entered '01 Jan 2006' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:56:06
Query 'Per source, medication was started 01Jan06. Please verify and update accordingly.' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:55:48
User opened query 'Per source, medication was started 01Jan06. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:51:49
User entered 'UN UNK 2006'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:12:01

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:51:52
User entered '0'	douglas winter (b) (4)	31 Oct 2020 16:12:01
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:51:58
User entered 'Yes (Y)'	douglas winter (b) (4)	31 Oct 2020 16:12:01
	(b) (4)	

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:07:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:52:02
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:12:01

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 16:12:01



**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:12:01

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:12:01

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Oct 2020 16:12:01

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:52:15
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 16:16:15
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 16:16:15
	(b) (4)	
Data point term sent to Coder	System	31 Oct 2020 16:15:19
User entered 'BACLOFEN'	douglas winter (b) (4)	31 Oct 2020 16:15:08
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 02:24:03
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:15:08

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. (Site from DM). Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'UPDATED' (Site from DM). User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6) Albert Garcia (b) (4) (b) (4), (b) (6)	28 Dec 2020 08:47:04 17 Dec 2020 17:09:14 16 Dec 2020 03:04:25
User entered 'MUSCLE SPASMS'	(b) (4), (b) (6) douglas winter (b) (4) (b) (4)	05 Nov 2020 16:52:20 31 Oct 2020 16:15:08

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:52:24
User entered '10'	douglas winter (b) (4)	31 Oct 2020 16:15:08
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:52:27
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:15:08



US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:07:28**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:52:31
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:15:08

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:52:35
User entered 'three times daily (TID)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:15:08

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:07:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:52:37
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:15:08

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:52:39
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:15:08

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:52:40
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:15:08

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Dec 2020 02:24:00
User closed query 'Re-query: As noted in previous query source notes start date of 01Apr2006. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:23:58
Query 'Re-query: As noted in previous query source notes start date of 01Apr2006. Please reconcile.' answered with 'UPDATED' (Site from CRA).	Albert Garcia (b) (4)	16 Nov 2020 13:23:32
	(b) (4)	
User entered '01 Apr 2006' reason for change: Data Entry Error	Albert Garcia (b) (4)	16 Nov 2020 13:23:26
	(b) (4)	
User opened query 'Re-query: As noted in previous query source notes start date of 01Apr2006. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:29:56
User closed query 'Per source, medication was started 01Apr06. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:29:56
Query 'Per source, medication was started 01Apr06. Please verify and update accordingly.' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4)	05 Nov 2020 19:55:20
	(b) (4)	
User entered '01 Jan 2006' reason for change: Data Entry Error	douglas winter (b) (4)	05 Nov 2020 19:54:58
	(b) (4)	
User opened query 'Per source, medication was started 01Apr06. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:53:21
User entered 'UN UNK 2006'	douglas winter (b) (4)	31 Oct 2020 16:15:08
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:53:25
User entered '0'	douglas winter (b) (4)	31 Oct 2020 16:15:08
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:53:30
User entered 'Yes (Y)'	douglas winter (b) (4)	31 Oct 2020 16:15:08
	(b) (4)	



US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:07:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:53:33
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:15:08

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:07:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 02:24:02
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:15:08

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	31 Oct 2020 16:15:08

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:15:08

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Oct 2020 16:15:08

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:53:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTI-DEMENTIA DRUGS, ATC: ANTICHOLINESTERASES, PRODUCT: DONEPEZIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 16:18:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 16:18:17
Data point term sent to Coder	System	31 Oct 2020 16:17:19
User entered 'DONEPEZIL'	douglas winter (b) (4)	31 Oct 2020 16:16:21
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	31 Oct 2020 16:16:21
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:53:46
User entered 'DEMENTIA'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:16:21



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:54:08
User entered '10'	douglas winter (b) (4)	31 Oct 2020 16:16:21
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:11
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:16:21

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:07:28**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:14
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:16:21

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:54:15
User entered 'once daily (QD)'	douglas winter (b) (4)	31 Oct 2020 16:16:21
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:18
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:16:21

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:20
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:16:21

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:07:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:22
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:16:21

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Per DM CLR-REQUERY: Response noted, however, please note that Con Med start date is prior to the start date of the Med History condition of DEMENTIA. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 19:46:48
Query 'Per DM CLR-REQUERY: Response noted, however, please note that Con Med start date is prior to the start date of the Med History condition of DEMENTIA. Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	17 Dec 2020 17:06:49
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	17 Dec 2020 17:06:36
User entered 'UN UNK 2013' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	17 Dec 2020 17:06:36
User opened query 'Per DM CLR-REQUERY: Response noted, however, please note that Con Med start date is prior to the start date of the Med History condition of DEMENTIA. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 03:07:08
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:30:13
User closed query 'Per source, medication started 01Jan12. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:30:10
Query 'Per source, medication started 01Jan12. Please verify and update accordingly.' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:57:06
User entered '01 Jan 2012' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:57:01
User opened query 'Per source, medication started 01Jan12. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:54:48
User entered 'UN UNK 2012'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:16:21



US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:54:51
User entered '0'	douglas winter (b) (4)	31 Oct 2020 16:16:21
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:54
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:16:21

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:56
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:16:21

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	31 Oct 2020 16:16:21
	(b) (4)	

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:16:21

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:16:21

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Oct 2020 16:16:21

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 16:20:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 16:20:23
Data point term sent to Coder	System	31 Oct 2020 16:19:20
User entered 'DULOXETINE'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:18:49



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	31 Oct 2020 16:18:49

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:18
User entered 'ANXIETY'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:18:49

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:20
User entered '40'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:18:49

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:21
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:18:49

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:23
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:18:49

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:30
User entered 'once daily (QD)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:18:49

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:32
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:18:49

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:35
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:18:49



US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:07:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:55:38
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:18:49

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:30:28
User closed query 'Per source, medication started 01Jan13. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:30:26
Query 'Per source, medication started 01Jan13. Please verify and update accordingly.' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:58:26
User entered '01 Jan 2013' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:58:14
User opened query 'Per source, medication started 01Jan13. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:56:13
User entered '30 Sep 2020'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:18:49

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:56:16
User entered '0'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:18:49

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:30:40
User closed query 'Per source, medication stopped 30Sep20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:30:38
Query 'Per source, medication stopped 30Sep20. Please verify and update accordingly.' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:58:31
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 19:58:14
User opened query 'Per source, medication stopped 30Sep20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:56:43
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:18:49

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:30:41
User entered '30 Sep 2020' reason for change: Data Entry Error	douglas winter (b) (4)	05 Nov 2020 19:58:14
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 16:18:49

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:07:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	31 Oct 2020 16:18:49

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User entered '1'	System	31 Oct 2020 16:18:49

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User entered '1'	System	31 Oct 2020 16:18:49



US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:04
User entered '804 (804)'	System	31 Oct 2020 16:18:49

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:57:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DIVALPROEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 16:22:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 16:22:12
	(b) (4)	
Data point term sent to Coder	System	31 Oct 2020 16:21:22
User entered 'DIVALPROEX'	douglas winter (b) (4)	31 Oct 2020 16:20:30
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	31 Oct 2020 16:20:30
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:19
User entered 'ANXIETY'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:20:30

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:21
User entered '250'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:20:30

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:23
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:20:30

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:07:28**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:57:25
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:20:30

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:57:27
User entered 'once daily (QD)'	douglas winter (b) (4)	31 Oct 2020 16:20:30
	(b) (4)	



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:58:16
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:20:30

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:58:21
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:20:30

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:58:22
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:20:30

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 02:30:56
User closed query 'Per source, start date is 01Jan13. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:30:54
Query 'Per source, start date is 01Jan13. Please verify and update accordingly.' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4)	05 Nov 2020 19:59:43
	(b) (4)	
User entered '01 Jan 2013' reason for change: Data Entry Error	douglas winter (b) (4)	05 Nov 2020 19:59:36
	(b) (4)	
User opened query 'Per source, start date is 01Jan13. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:58:52
User entered 'UN UNK 2013'	douglas winter (b) (4)	31 Oct 2020 16:20:30
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:58:57
User entered '0'	douglas winter (b) (4)	31 Oct 2020 16:20:30
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:59:00
User entered 'Yes (Y)'	douglas winter (b) (4)	31 Oct 2020 16:20:30
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:59:03
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:20:30

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:07:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	31 Oct 2020 16:20:30
	(b) (4)	



**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:20:30

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:20:30

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Oct 2020 16:20:30

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Jan 2021 20:26:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 20:26:14
Data point term sent to Coder	System	20 Jan 2021 20:25:00
Coding entries removed.	(b) (4), (b) (6)	20 Jan 2021 20:24:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:03:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 16:23:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 16:23:13
Data point term sent to Coder	System	31 Oct 2020 16:22:22
User entered 'FUROSEMIDE'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:21:33

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:22:25
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:55:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:55:39
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 22:34:44
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:21:33

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Per CDM: Response noted however, it appears no updates have been made. Kindly review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 14:24:44
Query 'Per CDM: Response noted however, it appears no updates have been made. Kindly review and update accordingly.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 20:24:43
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 20:24:34
User entered 'HYPERTENSION' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 20:24:34
User opened query 'Per CDM: Response noted however, it appears no updates have been made. Kindly review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 21:15:37
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 21:15:37
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'THIS MEDICATION IS TAKEN AS TREATMENT FOR HTN, WHICH IS NOTED ON THE MH PAGE. PLEASE REVIEW. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	17 Dec 2020 17:11:33
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 03:07:27

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:03:11
User entered 'DIURETIC'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:21:33

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:03:16
User entered '20'	douglas winter (b) (4)	31 Oct 2020 16:21:33
	(b) (4)	



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:03:21
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:21:33

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:07:28**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:03:24
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:21:33

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:03:26
User entered 'once daily (QD)'	douglas winter (b) (4)	31 Oct 2020 16:21:33
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:03:28
User entered empty.	douglas winter (b) (4)	31 Oct 2020 16:21:33
	(b) (4)	

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:07:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:03:33
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:21:33

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:07:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:03:36
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:21:33

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Per source, medication started 01Jan11. Please verify and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:31:10
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:31:09
Query 'Per source, medication started 01Jan11. Please verify and update accordingly.' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4) (b) (4)	05 Nov 2020 20:00:41
User entered '01 Jan 2011' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 20:00:34
User opened query 'Per source, medication started 01Jan11. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:04:10
User entered 'UN UNK 2011'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:21:33

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:04:15
User entered '0'	douglas winter (b) (4)	31 Oct 2020 16:21:33
	(b) (4)	



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:20
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:21:33

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:07:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:22
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:21:33

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:07:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	31 Oct 2020 16:21:33
	(b) (4)	

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:21:33

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:21:33

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Oct 2020 16:21:33

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:04:29
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 03:25:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 03:25:44
	(b) (4)	
Data point term sent to Coder	System	31 Oct 2020 16:23:22
User entered 'LEVOTHYROXINE'	douglas winter (b) (4)	31 Oct 2020 16:23:20
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	31 Oct 2020 16:23:20
	(b) (4)	



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:31
User entered 'HYPOPARATHYROID'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:23:20

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 02:31:24
User closed query 'Per source, dose is .88. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:31:22
Query 'Per source, dose is .88. Please verify and update accordingly. ' answered with 'UPDATED' (Site from CRA).	douglas winter (b) (4)	05 Nov 2020 20:01:24
	(b) (4)	
User entered '0.88' reason for change: Data Entry Error	douglas winter (b) (4)	05 Nov 2020 20:01:14
	(b) (4)	
User opened query 'Per source, dose is .88. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:05:10
User entered '88'	douglas winter (b) (4)	31 Oct 2020 16:23:20
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:05:15
User entered 'ug (ug)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:23:20

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:07:28**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:05:18
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:23:20

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:05:22
User entered 'once daily (QD)'	douglas winter (b) (4)	31 Oct 2020 16:23:20
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:05:25
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:23:20

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:05:27
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:23:20

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:07:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:05:29
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:23:20



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 02:31:35
User closed query 'Per source, start date is 01Jan18. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:31:33
User entered '01 Jan 2018' reason for change: Data Entry Error	douglas winter (b) (4)	05 Nov 2020 20:01:44
	(b) (4)	
Query 'Per source, start date is 01Jan18. Please verify and update accordingly. ' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4)	05 Nov 2020 20:01:30
	(b) (4)	
User opened query 'Per source, start date is 01Jan18. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:06:57
User entered 'UN UNK 2018'	douglas winter (b) (4)	31 Oct 2020 16:23:20
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:15:50
User entered '0'	douglas winter (b) (4)	31 Oct 2020 16:23:20
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:15:52
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:23:20

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:15:54
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:23:20

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:07:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	31 Oct 2020 16:23:20
	(b) (4)	

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:23:20

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:23:20

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Oct 2020 16:23:20



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:26:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 16:26:13
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 16:26:13
	(b) (4)	
Data point term sent to Coder	System	31 Oct 2020 16:25:24
User entered 'METOPROLOL'	douglas winter (b) (4)	31 Oct 2020 16:25:22
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	31 Oct 2020 16:25:22
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:27:00
User entered 'HYPERTENSION'	douglas winter (b) (4)	31 Oct 2020 16:25:22
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:27:05
User entered '25'	douglas winter (b) (4)	31 Oct 2020 16:25:22
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:39:58
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:25:22

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:07:28**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:40:09
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:25:22

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:40:11
User entered 'twice daily (BID)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:25:22

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:07:28**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:40:13
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:25:22



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:40:21
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:25:22

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:07:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:40:23
User entered empty.	douglas winter (b) (4)	31 Oct 2020 16:25:22
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Per DM CLR-REQUERY: Response noted, however, please note that Con Med start date is prior to the start date of the Med History condition of HYPERTENSION. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 08:54:30
Query 'Per DM CLR-REQUERY: Response noted, however, please note that Con Med start date is prior to the start date of the Med History condition of HYPERTENSION. Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	17 Dec 2020 17:12:57
DataPoint Un-verified.	Albert Garcia (b) (4) (b) (4)	17 Dec 2020 17:12:38
User entered 'UN UNK 2000' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	17 Dec 2020 17:12:38
User opened query 'Per DM CLR-REQUERY: Response noted, however, please note that Con Med start date is prior to the start date of the Med History condition of HYPERTENSION. Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 03:08:04
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:31:48
User closed query 'Per source, start date is 01Jan1988. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:31:46
Query 'Per source, start date is 01Jan1988. Please verify and update accordingly.' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4) (b) (4)	05 Nov 2020 20:02:18
User entered '01 Jan 1988' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 20:02:13
User opened query 'Per source, start date is 01Jan1988. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:40:52
User entered 'UN UNK 1988'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:25:22

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:40:55
User entered '0'	douglas winter (b) (4)	31 Oct 2020 16:25:22
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:41:04
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:25:22

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:07:28**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:41:10
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:25:22

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:07:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	31 Oct 2020 16:25:22
	(b) (4)	

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	31 Oct 2020 16:25:22



US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:25:22

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Oct 2020 16:25:22

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:41:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTI-DEMENTIA DRUGS, ATC: OTHER ANTI-DEMENTIA DRUGS, PRODUCT: MEMANTINE HYDROCHLORIDE, PRODUCTSYNONYM: NAMENDA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 16:57:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 16:57:19
	(b) (4)	
Data point term sent to Coder	System	31 Oct 2020 16:56:30
User entered 'NAMENDA'	douglas winter (b) (4)	31 Oct 2020 16:55:56
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	31 Oct 2020 16:55:56
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:41:20
User entered 'DEMENTIA'	douglas winter (b) (4)	31 Oct 2020 16:55:56
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:41:22
User entered '10'	douglas winter (b) (4)	31 Oct 2020 16:55:56
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:41:23
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:55:56

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:07:28**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:41:25
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:55:56



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:41:27
User entered 'twice daily (BID)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:55:56

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:41:31
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:55:56

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:41:33
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:55:56

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:07:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:41:35
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:55:56

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 02:32:01
User closed query 'Per source, medication started 01Jan13. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:31:59
Query 'Per source, medication started 01Jan13. Please verify and update accordingly.' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4)	05 Nov 2020 20:03:05
	(b) (4)	
User entered '01 Jan 2013' reason for change: Data Entry Error	douglas winter (b) (4)	05 Nov 2020 20:02:53
	(b) (4)	
User opened query 'Per source, medication started 01Jan13. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:42:05
User entered 'UN UNK 2013'	douglas winter (b) (4)	31 Oct 2020 16:55:56
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:42:09
User entered '0'	douglas winter (b) (4)	31 Oct 2020 16:55:56
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:42:12
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:55:56

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:42:14
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:55:56



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:07:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	31 Oct 2020 16:55:56
	(b) (4)	

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	31 Oct 2020 16:55:56

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:55:56

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Oct 2020 16:55:56

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 14:33:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 14:33:19
Data point term sent to Coder	System	23 Apr 2021 14:10:53
Coding entries removed.	(b) (4), (b) (6)	23 Apr 2021 14:10:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Feb 2021 22:01:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Feb 2021 22:01:42
Data point term sent to Coder	System	12 Feb 2021 12:04:44
Coding entries removed.	Alicia Cevera (b) (4)	12 Feb 2021 12:03:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 06:09:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 06:09:40
Data point term sent to Coder	System	05 Nov 2020 20:21:05

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EAB) (1725)

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US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	douglas winter (b) (4)	05 Nov 2020 20:20:51
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:43:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 16:58:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 16:58:20
	(b) (4)	
Data point term sent to Coder	System	31 Oct 2020 16:57:31
User entered 'OMEPRAZOLE'	douglas winter (b) (4)	31 Oct 2020 16:57:05
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Per CDM: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please reconcile both CM and MH pages and update accordingly, Otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 09:08:59
Query 'Per CDM: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please reconcile both CM and MH pages and update accordingly, Otherwise provide clarification. ' answered with 'corrected and updated. Subject taking medication for indication that is recorded in MH eCRF and MH source' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 14:11:41
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 14:10:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 14:10:20
User opened query 'Per CDM: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please reconcile both CM and MH pages and update accordingly, Otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 15:24:50
Query 'Per CDM: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the MH record should be removed as appropriate. Otherwise, provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 15:22:43
User opened query 'Per CDM: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the MH record should be removed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 15:05:21
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:32:21
User closed query 'Per source, this is taken for prophylaxis. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:32:19

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Query 'Per source, this is taken for prophylaxis. Please verify and update accordingly.' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4) (b) (4)	05 Nov 2020 20:21:28
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	05 Nov 2020 20:21:17
User opened query 'Per source, this is taken for prophylaxis. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4)	05 Nov 2020 17:45:26
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:57:05



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'GASTRODUODENAL ULCER' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:10:20
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF (GASTRODUODENAL ULCER ). Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 15:03:19
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF (GASTRODUODENAL ULCER ). Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:59:10
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF (GASTRODUODENAL ULCER ). Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 15:18:59
User closed query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. Prophylaxis for Gastroduodenal ulcer). Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 15:04:05
Query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. Prophylaxis for Gastroduodenal ulcer). Update Con Med eCRF as appropriate' answered with 'UPDATED' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:04:01
DataPoint Un-verified.	Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:03:53
User entered 'GASTRODUODENAL ULCER PROPHYLAXIS' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:03:53
User opened query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. Prophylaxis for Gastroduodenal ulcer). Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 19:15:13

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. Prophylaxis for Gastroduodenal XXX). Update Con Med eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 19:15:03
User opened query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. Prophylaxis for Gastroduodenal XXX). Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	28 Jan 2021 19:13:55
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:32:16
User closed query 'Per source, indication the is prophylaxis. Please verify and update accordingly. '	(b) (4), (b) (6)	16 Nov 2020 02:32:14
(Site from CRA).		
Query 'Per source, indication the is prophylaxis. Please verify and update accordingly. ' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4)	05 Nov 2020 20:21:33
	(b) (4)	
User entered 'GASTRODUODENAL PROPHYLAXIS' reason for change: Data Entry Error	douglas winter (b) (4)	05 Nov 2020 20:20:51
	(b) (4)	
User opened query 'Per source, indication the is prophylaxis. Please verify and update accordingly. '	(b) (4), (b) (6)	05 Nov 2020 17:47:39
(Site from CRA).		
User entered 'GERD'	douglas winter (b) (4)	31 Oct 2020 16:57:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:47:54
User entered '40'	douglas winter (b) (4)	31 Oct 2020 16:57:05
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:47:56
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:57:05

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:47:59
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:57:05

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:48:01
User entered 'once daily (QD)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:57:05

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:48:41
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:57:05

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:48:44
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:57:05



US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:07:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:48:54
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:57:05

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Dec 2020 02:24:24
User closed query 'Re-query: Per previous query - Per source, start date is 01Apr20. Please verify and update accordingly. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:24:23
Query 'Re-query: Per previous query - Per source, start date is 01Apr20. Please verify and update accordingly. Please reconcile.' answered with 'UPDATED' (Site from CRA).	Albert Garcia (b) (4)	16 Nov 2020 13:30:44
	(b) (4)	
User entered '01 Apr 2020' reason for change: Data Entry Error	Albert Garcia (b) (4)	16 Nov 2020 13:30:33
	(b) (4)	
User opened query 'Re-query: Per previous query - Per source, start date is 01Apr20. Please verify and update accordingly. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:33:03
User closed query 'Per source, start date is 01Apr20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:33:03
Query 'Per source, start date is 01Apr20. Please verify and update accordingly.' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4)	05 Nov 2020 20:21:40
	(b) (4)	
User entered '01 Apr 2006' reason for change: Data Entry Error	douglas winter (b) (4)	05 Nov 2020 20:21:09
	(b) (4)	
User opened query 'Per source, start date is 01Apr20. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:50:47
User entered 'UN Apr 2006'	douglas winter (b) (4)	31 Oct 2020 16:57:05
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:50:49
User entered '0'	douglas winter (b) (4)	31 Oct 2020 16:57:05
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:50:52
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:57:05

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:50:58
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:57:05

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:07:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 02:24:26
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:57:05

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:57:05

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:57:05



US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Oct 2020 16:57:05

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:51:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 17:00:20
User coded data point as Term Coded data point by	Coder Import (b) (4)	31 Oct 2020 17:00:20
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	31 Oct 2020 16:59:31
User entered 'ROSUVASTATIN'	douglas winter (b) (4)	31 Oct 2020 16:58:41
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'No (N)'	douglas winter (b) (4)	31 Oct 2020 16:58:41
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:51:12
User entered 'HYPERLIPIDEMIA'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:58:41

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:51:14
User entered '10'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:58:41

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:51:17
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:58:41

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:07:28**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:51:18
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:58:41

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:51:20
User entered 'once daily (QD)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:58:41



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:51:22
User entered empty.	douglas winter (b) (4)	31 Oct 2020 16:58:41
	(b) (4)	

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:07:28**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:51:24
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:58:41

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:07:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:51:26
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:58:41

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 02:33:23
User closed query 'Per source, medication start date is 01Jan06. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:33:21
Query 'Per source, medication start date is 01Jan06. Please verify and update accordingly.' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4)	05 Nov 2020 20:35:17
	(b) (4)	
User entered '01 Jan 2006' reason for change: Data Entry Error	douglas winter (b) (4)	05 Nov 2020 20:35:11
	(b) (4)	
User opened query 'Per source, medication start date is 01Jan06. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:52:04
User entered 'UN UNK 2006'	douglas winter (b) (4)	31 Oct 2020 16:58:41
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:52:13
User entered '0'	douglas winter (b) (4)	31 Oct 2020 16:58:41
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:52:18
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:58:41

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:52:20
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:58:41

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:07:28**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4) (b) (4)	31 Oct 2020 16:58:41



US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:58:41

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:58:41

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Oct 2020 16:58:41

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Per source, Cefdinir, Tramadol and Bactrim were given for the SAE. Please verify and update log accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 02:35:12
Query 'Per source, Cefdinir, Tramadol and Bactrim were given for the SAE. Please verify and update log accordingly.' answered with 'THIS HAS BEEN UPDATED' (Site from CRA).	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:19:56
User opened query 'Per source, Cefdinir, Tramadol and Bactrim were given for the SAE. Please verify and update log accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:54:30
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:52:29
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: TOLTERODINE L-TARTRATE, PRODUCTSYNONYM: DETROL LA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 17:01:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 17:01:20
Data point term sent to Coder	System	31 Oct 2020 17:00:31
User entered 'DETROL LA'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:59:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 02:24:33
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:59:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:52:31
User entered 'URINARY INCONTINENCE'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:59:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:52:35
User entered '4'	douglas winter (b) (4)	31 Oct 2020 16:59:54
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:52:37
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:59:54



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:52:39
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:59:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:52:42
User entered 'once daily (QD)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:59:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:52:45
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:59:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:52:47
User entered 'Oral (ORAL)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:59:54

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:07:28**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:52:51
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:59:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Dec 2020 02:24:44
User closed query 'Re-query: Per previous query the start date in sources noted 01Jan2006 but you entered 01UNK2006 in EDC. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:24:42
Query 'Re-query: Per previous query the start date in sources noted 01Jan2006 but you entered 01UNK2006 in EDC. Please reconcile.' answered with 'UPDATED' (Site from CRA).	Albert Garcia (b) (4)	16 Nov 2020 13:31:33
	(b) (4)	
User entered '01 Jan 2006' reason for change: Data Entry Error	Albert Garcia (b) (4)	16 Nov 2020 13:31:23
	(b) (4)	
User opened query 'Re-query: Per previous query the start date in sources noted 01Jan2006 but you entered 01UNK2006 in EDC. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:34:17
User closed query 'Per source, start date is 01Jan06. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:34:17
Query 'Per source, start date is 01Jan06. Please verify and update accordingly.' answered with 'UPDATED TO MATCH SOURCE' (Site from CRA).	douglas winter (b) (4)	05 Nov 2020 20:36:45
	(b) (4)	
User entered '01 UNK 2006' reason for change: Data Entry Error	douglas winter (b) (4)	05 Nov 2020 20:36:37
	(b) (4)	
User opened query 'Per source, start date is 01Jan06. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:53:20
User entered 'UN UNK 2006'	douglas winter (b) (4)	31 Oct 2020 16:59:54
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:53:29
User entered '0'	douglas winter (b) (4)	31 Oct 2020 16:59:54
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:53:33
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:59:54



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:53:34
User entered empty.	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:59:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:07:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 02:24:47
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	31 Oct 2020 16:59:54

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:59:54

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 16:59:54

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Oct 2020 16:59:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 21:01:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 21:01:26
Data point term sent to Coder	System	05 Nov 2020 20:45:33
User entered 'CEFDINIR'	douglas winter (b) (4)	05 Nov 2020 20:45:20

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	05 Nov 2020 20:45:20
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'URINARY TRACT INFECTION'	(b) (4) douglas winter (b) (4)	05 Nov 2020 20:45:20



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '300'	(b) (4) douglas winter (b) (4)	05 Nov 2020 20:45:20

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4)	05 Nov 2020 20:45:20

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) douglas winter (b) (4)	05 Nov 2020 20:45:20
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'twice daily (BID)'	(b) (4) douglas winter (b) (4)	05 Nov 2020 20:45:20

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) douglas winter (b) (4)	05 Nov 2020 20:45:20
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	05 Nov 2020 20:45:20
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) douglas winter (b) (4)	05 Nov 2020 20:45:20
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '30 Sep 2020'	(b) (4) douglas winter (b) (4)	05 Nov 2020 20:45:20
	(b) (4)	



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	05 Nov 2020 20:45:20

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	10 Nov 2020 20:20:38
User entered 'Yes (Y)'	(b) (4)	
	douglas winter (b) (4)	05 Nov 2020 20:45:20
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '5 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	10 Nov 2020 20:20:38
User entered empty.	(b) (4)	
	douglas winter (b) (4)	05 Nov 2020 20:45:20
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	05 Nov 2020 20:45:20

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User entered '2'	System	05 Nov 2020 20:45:20

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:07:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User entered '1'	System	05 Nov 2020 20:45:20

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:14
User entered '804 (804)'	System	05 Nov 2020 20:45:20

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Mar 2021 14:23:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Mar 2021 14:23:05
Data point term sent to Coder	System	12 Feb 2021 12:22:45
Coding entries removed.	Alicia Cevera (b) (4)	12 Feb 2021 12:22:00
User closed query 'Please verify if you mean this to be TRAMADOL' (Site from CRA).	(b) (4)	29 Dec 2020 02:24:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Nov 2020 13:34:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Nov 2020 13:34:43
Data point term sent to Coder	System	16 Nov 2020 13:33:26
Data point term sent to Coder	System	16 Nov 2020 13:32:25
Query 'Please verify if you mean this to be TRAMADOL' answered with 'UPDATED' (Site from CRA).	Albert Garcia (b) (4)	16 Nov 2020 13:32:07
Coding entries removed.	Albert Garcia (b) (4)	16 Nov 2020 13:32:02
User entered 'TRAMADOL' reason for change: Data Entry Error	Albert Garcia (b) (4)	16 Nov 2020 13:32:02
User opened query 'Please verify if you mean this to be TRAMADOL' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:34:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 05:01:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Nov 2020 05:01:47
Data point term sent to Coder	System	10 Nov 2020 20:21:42

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EAB) (1725)

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:07:28**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'TRAMSDOL'	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:21:31

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	Albert Garcia (b) (4)	10 Nov 2020 20:21:31

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Per CDM: Response noted "UPDATED PER PATIENT". However update is not obvious please provide location of update such as log line number.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 10:02:44
Query 'Per CDM: Response noted "UPDATED PER PATIENT". However update is not obvious please provide location of update such as log line number.' answered with 'AE log line 2' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:02:30
User opened query 'Per CDM: Response noted "UPDATED PER PATIENT". However update is not obvious please provide location of update such as log line number.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 15:06:54
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)	15 Feb 2021 15:06:54
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 'UPDATED PER PATIENT' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:22:22
User entered 'POSTOPERATIVE HIP PAIN' reason for change: Data Entry Error	Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:22:00
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)	28 Jan 2021 19:16:05
User closed query 'Per CDM: Please update the indication to include the type and location of 'PAIN' and update Med Hist/AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 16:45:07

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
Query 'Per CDM: Please update the indication to include the type and location of 'PAIN' and update Med Hist/AE eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	16 Nov 2020 13:33:11
User entered 'HIP PAIN' reason for change: Data Entry Error	Albert Garcia (b) (4)	16 Nov 2020 13:33:06
User opened query 'Per CDM: Please update the indication to include the type and location of 'PAIN' and update Med Hist/AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 10:19:27
User entered 'PAIN'	Albert Garcia (b) (4)	10 Nov 2020 20:21:31

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '50'	Albert Garcia (b) (4)	10 Nov 2020 20:21:31

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'mg (mg)'	Albert Garcia (b) (4)	10 Nov 2020 20:21:31

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	Albert Garcia (b) (4)	10 Nov 2020 20:21:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'as needed (PRN)'	Albert Garcia (b) (4)	10 Nov 2020 20:21:31



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	Albert Garcia (b) (4)	10 Nov 2020 20:21:31

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:07:28**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	10 Nov 2020 20:21:31

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	Albert Garcia (b) (4)	10 Nov 2020 20:21:31

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '29 Sep 2020'	Albert Garcia (b) (4)	10 Nov 2020 20:21:31

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	Albert Garcia (b) (4)	10 Nov 2020 20:21:31

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	Albert Garcia (b) (4)	10 Nov 2020 20:21:31

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '12 Oct 2020'	Albert Garcia (b) (4)	10 Nov 2020 20:21:31

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:07:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	Albert Garcia (b) (4)	10 Nov 2020 20:21:31



**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User entered empty.	System	10 Nov 2020 20:21:31

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User entered empty.	System	10 Nov 2020 20:21:31

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User entered empty.	System	10 Nov 2020 20:21:31

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:07:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 17:31:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 17:31:45
Data point term sent to Coder	System	17 Dec 2020 17:31:08
Coding entries removed.	Albert Garcia (b) (4)	17 Dec 2020 17:30:52
User entered 'BACTRIM - Trimethoprim / Sulfamethoxazole' reason for change: Data Entry Error	Albert Garcia (b) (4)	17 Dec 2020 17:30:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 20:38:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 20:38:42
Data point term sent to Coder	System	10 Nov 2020 20:22:49
User entered 'BACTRIM'	Albert Garcia (b) (4)	10 Nov 2020 20:22:25

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4)	10 Nov 2020 20:22:25

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:07:28**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'UTI'	Albert Garcia (b) (4)	10 Nov 2020 20:22:25

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Dec 2020 09:44:20
Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	17 Dec 2020 17:31:16
User entered 'UNK' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	17 Dec 2020 17:30:52
User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 03:08:52
User entered '60'	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:22:25

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'mg (mg)'	Albert Garcia (b) (4)	10 Nov 2020 20:22:25



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:07:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) Albert Garcia (b) (4)	10 Nov 2020 20:22:25

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'three times daily (TID)'	Albert Garcia (b) (4)	10 Nov 2020 20:22:25

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	Albert Garcia (b) (4)	10 Nov 2020 20:22:25

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:07:28**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	10 Nov 2020 20:22:25

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:07:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	Albert Garcia (b) (4)	10 Nov 2020 20:22:25

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE#1 (30SEP2020) and prior to the start date of the AE#3 (4DEC2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 10:38:55
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE#1 (30SEP2020) and prior to the start date of the AE#3 (4DEC2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'subject states she was released from hospital and a second course of antibiotics was given by pcip' (Site from DM).	Alicia Cevera (b) (4) (b) (4)	12 Feb 2021 12:57:02
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE#1 (30SEP2020) and prior to the start date of the AE#3 (4DEC2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 19:20:59
User entered '5 Oct 2020'	Albert Garcia (b) (4) (b) (4)	10 Nov 2020 20:22:25

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:07:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	Albert Garcia (b) (4)	10 Nov 2020 20:22:25

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:07:28**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4)	10 Nov 2020 20:22:25



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '12 Oct 2020'	Albert Garcia (b) (4)	10 Nov 2020 20:22:25

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:07:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	Albert Garcia (b) (4)	10 Nov 2020 20:22:25

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User entered '3'	System	10 Nov 2020 20:22:25

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User entered '1'	System	10 Nov 2020 20:22:25

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:26
User entered '804 (804)'	System	10 Nov 2020 20:22:25

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:07:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 18:05:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 18:05:05
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	08 Apr 2021 18:04:10 08 Apr 2021 18:03:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 20:22:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 20:22:22
Data point term sent to Coder User entered 'INFLUENZA'	System (b) (4), (b) (6)	20 Jan 2021 20:20:42 20 Jan 2021 20:19:47

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:47

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:23:11
Query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:03:46
User entered 'prophylaxis SEASONAL INFLUENZA' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:03:38
User opened query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 22:34:56
User entered 'SEASONAL INFLUENZA'	(b) (4), (b) (6)	20 Jan 2021 20:19:47



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0.5'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:47

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:47

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:07:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:47

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:07:28**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:47

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:47

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:07:28**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:47

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:07:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:47

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4)	20 Jan 2021 20:22:30
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 20:19:47



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:22:30
User entered '1'	(b) (4), (b) (6)	20 Jan 2021 20:19:47

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:07:28**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:47

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	20 Jan 2021 20:22:30
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 20:22:30
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	20 Jan 2021 20:19:47
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 20:19:47

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:07:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 20:19:47

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User entered empty.	System	20 Jan 2021 20:19:47

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User entered empty.	System	20 Jan 2021 20:19:47

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:32
User entered empty.	System	20 Jan 2021 20:19:47

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:07:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LEVAQUIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 04:01:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 04:01:51
Data point term sent to Coder	System	08 Apr 2021 17:55:56
User entered 'Levaquin'	(b) (4), (b) (6)	08 Apr 2021 17:55:17



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:55:17

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:07:28**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'UTI'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:55:17

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:07:28**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '500'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:55:17

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:55:17

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:07:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:55:17

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:55:17

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:55:17

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:07:28**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:55:17



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:07:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:55:17

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '05 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:55:17

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:07:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:55:17

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:07:28**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:55:17

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:55:17

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:07:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:55:17

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User entered '1'	System	08 Apr 2021 17:55:17

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User entered '1'	System	08 Apr 2021 17:55:17



US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:37
User entered '804 (804)'	System	08 Apr 2021 17:55:17

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Apr 2021 04:34:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 04:34:33
Data point term sent to Coder	System	08 Apr 2021 18:06:15
User entered 'tramadol'	(b) (4), (b) (6)	08 Apr 2021 18:05:14

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:07:28**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:14

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:07:28**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'knee pain'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:14

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:07:28**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '50'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:14

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:14

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:14

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:07:28**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:14



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:14

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:14

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:14

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:07:28**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:14

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:07:28**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:14

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Apr 2021 18:05:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Apr 2021 18:05:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:05:22
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 18:05:14
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 18:05:14

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:07:28**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:14

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:05:14



US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User entered empty.	System	08 Apr 2021 18:05:14

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:07:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User entered empty.	System	08 Apr 2021 18:05:14

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:43
User entered empty.	System	08 Apr 2021 18:05:14

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALOXIN, PRODUCTSYNONYM: CEPHALOXIN [CEFALOXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Apr 2021 13:36:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Apr 2021 13:36:01
Data point term sent to Coder	System	24 Apr 2021 13:20:21
Data point term sent to Coder	System	24 Apr 2021 13:10:19
User entered 'CEPHALOXIN'	douglas winter (b) (4)	24 Apr 2021 13:10:00

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:10:00

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'PRE-OP MOHS SURGERY BASAL CELL CARCINOMA EXCISED FROM CHEAK.'	(b) (4)	
douglas winter (b) (4)	(b) (4)	24 Apr 2021 13:20:08
reason for change: Data Entry Error		
User entered 'PRE-OP BASAL CELL CARCINOMA EXCISED FROM CHEAK.'	douglas winter (b) (4)	24 Apr 2021 13:10:00
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '500'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:10:00

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:10:00



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:10:00

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:10:00

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Q6-12HS X 4'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:10:00

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:10:00
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:10:00

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '01 Feb 2021'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:10:00

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:10:00

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:10:00



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '02 Feb 2021'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:10:00

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:07:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:10:00

**US3222311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User entered empty.	System	24 Apr 2021 13:10:00

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User entered empty.	System	24 Apr 2021 13:10:00

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:49
User entered empty.	System	24 Apr 2021 13:10:00

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Apr 2021 13:37:01
	(b) (4)	
Data point term sent to Coder	System	24 Apr 2021 13:21:21
Data point term sent to Coder	System	24 Apr 2021 13:14:20
User entered 'DOXYCYCLINE'	douglas winter (b) (4)	24 Apr 2021 13:13:54
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:13:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'MOHS SURGERY FOR BASAL CELL REMOVED' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:20:31
User entered 'MOHS SURGERY FOR BASAL CELL REMOVAL'	douglas winter (b) (4) (b) (4)	24 Apr 2021 13:13:54



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '100'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:13:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:13:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:13:54
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:13:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'QD X 5 DAYS'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:13:54
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:13:54
	(b) (4)	

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered empty.	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:13:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '02 Feb 2021'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:13:54
	(b) (4)	



US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:13:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:13:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered '07 Feb 2021'	(b) (4) douglas winter (b) (4) (b) (4)	24 Apr 2021 13:13:54

US3222311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:07:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	24 Apr 2021 13:13:54

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:07:28**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User entered empty.	System	24 Apr 2021 13:13:54

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User entered empty.	System	24 Apr 2021 13:13:54

US3222311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 16:07:28**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:53
User entered empty.	System	24 Apr 2021 13:13:54

US3222311

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:07:28

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:12
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
Signature has been broken.	douglas winter (b) (4)	24 Apr 2021 13:23:06
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	24 Apr 2021 13:23:06
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'No (N)'	Amber Vasquez (b) (4)	10 Oct 2020 22:14:52



US3222311

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:07:28**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered '02 Feb 2021'	douglas winter (b) (4)	24 Apr 2021 13:26:14
	(b) (4)	

US3222311

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'MOHS SURGERY'	douglas winter (b) (4)	24 Apr 2021 13:26:14
	(b) (4)	

US3222311

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:07:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered 'Adverse Event (AE)'	douglas winter (b) (4)	24 Apr 2021 13:26:14
	(b) (4)	

US3222311

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:07:28

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 14:08:14
	(b) (4)	
User entered empty.	douglas winter (b) (4)	24 Apr 2021 13:26:14
	(b) (4)	

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered		
'USA-US104-2020-MRNA-1273-P301000012'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Yes (Y)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:55:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17



**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:55:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Yes (Y)'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:56:22
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:00:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Bruce'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
User entered 'Lisa'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered 'Tracy'	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
Un-reviewed for Safety.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Tracy'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Rankin'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
User entered 'Holloway'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered 'Kowalski'	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
Un-reviewed for Safety.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Kowalski'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered '860 Peachwood Ave'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered empty.	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered '860 Peachwood Drive'	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Deland'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered 'Houston'	System	03 Dec 2020 15:03:10
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
	(b) (4)	
User entered empty.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	



US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered empty.	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered 'TX'	System	03 Dec 2020 15:03:10
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
	(b) (4)	
User entered empty.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered '32720'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered '77081'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:01:03
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered empty.	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered '32720'	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:01:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered 'US'	System	12 Oct 2020 14:57:55

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
User entered '4'	System	03 Dec 2020 15:03:10
User entered '3'	System	11 Nov 2020 17:14:07
User entered '2'	System	02 Nov 2020 19:37:18
User entered '1'	System	12 Oct 2020 14:57:55

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered		
'USA-US104-2020-MRNA-1273-P301000012'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:55:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Yes (Y)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:55:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17



**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:55:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Yes (Y)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:55:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:56:22
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:00:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Bruce'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
User entered 'Lisa'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered 'Tracy'	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
Un-reviewed for Safety.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Tracy'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Rankin'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
User entered 'Holloway'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered 'Kowalski'	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
Un-reviewed for Safety.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Kowalski'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered '860 Peachwood Ave'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered empty.	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered '860 Peachwood Drive'	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Deland'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered 'Houston'	System	03 Dec 2020 15:03:10
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
	(b) (4)	
User entered empty.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	



US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered empty.	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered 'TX'	System	03 Dec 2020 15:03:10
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
	(b) (4)	
User entered empty.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered '32720'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered '77081'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:01:03
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered empty.	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered '32720'	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:01:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered 'US'	System	12 Oct 2020 14:57:55

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
User entered '4'	System	03 Dec 2020 15:03:10
User entered '3'	System	11 Nov 2020 17:14:07
User entered '2'	System	02 Nov 2020 19:37:18
User entered '1'	System	12 Oct 2020 14:57:55

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:07:28**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '12/Oct/2020 14:57'	(b) (4) System	12 Oct 2020 14:57:55

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:07:28

**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)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 14:57:55

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered		
'USA-US104-2020-MRNA-1273-P301000012'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Yes (Y)'	System	12 Oct 2020 14:57:17



**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:55:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Yes (Y)'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:56:22
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:00:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Bruce'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
User entered 'Lisa'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered 'Tracy'	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
Un-reviewed for Safety.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Tracy'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Rankin'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
User entered 'Holloway'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered 'Kowalski'	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
Un-reviewed for Safety.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Kowalski'	System	12 Oct 2020 14:57:17



US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered '860 Peachwood Ave'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered empty.	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered '860 Peachwood Drive'	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Deland'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered 'Houston'	System	03 Dec 2020 15:03:10
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
	(b) (4)	
User entered empty.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered empty.	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered 'TX'	System	03 Dec 2020 15:03:10
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
	(b) (4)	
User entered empty.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered '32720'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered '77081'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:01:03
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered empty.	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered '32720'	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:01:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered 'US'	System	12 Oct 2020 14:57:55

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
User entered '4'	System	03 Dec 2020 15:03:10
User entered '3'	System	11 Nov 2020 17:14:07
User entered '2'	System	02 Nov 2020 19:37:18
User entered '1'	System	12 Oct 2020 14:57:55

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:07:28**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '02/Nov/2020 19:37'	(b) (4) System	02 Nov 2020 19:37:18

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:07:28

**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)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:13:53
User entered 'I'	(b) (4), (b) (6)	02 Nov 2020 19:37:18



**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered		
'USA-US104-2020-MRNA-1273-P301000012'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Yes (Y)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Yes (Y)'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:56:22
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:00:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17



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Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Bruce'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
User entered 'Lisa'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered 'Tracy'	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
Un-reviewed for Safety.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Tracy'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Rankin'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
User entered 'Holloway'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered 'Kowalski'	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
Un-reviewed for Safety.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Kowalski'	System	12 Oct 2020 14:57:17

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Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered '860 Peachwood Ave'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered empty.	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered '860 Peachwood Drive'	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Deland'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered 'Houston'	System	03 Dec 2020 15:03:10
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
	(b) (4)	
User entered empty.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered empty.	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered 'TX'	System	03 Dec 2020 15:03:10
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
	(b) (4)	
User entered empty.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered '32720'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered '77081'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:01:03
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered empty.	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered '32720'	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:01:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered 'US'	System	12 Oct 2020 14:57:55

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Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
User entered '4'	System	03 Dec 2020 15:03:10
User entered '3'	System	11 Nov 2020 17:14:07
User entered '2'	System	02 Nov 2020 19:37:18
User entered '1'	System	12 Oct 2020 14:57:55



**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:07:28**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '11/Nov/2020 12:14'	(b) (4) System	11 Nov 2020 17:14:07

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Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:07:28

**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)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:02:58
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 17:14:07

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered		
'USA-US104-2020-MRNA-1273-P301000012'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

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**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Yes (Y)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:55:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Yes (Y)'	System	12 Oct 2020 14:57:17

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17



**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:56:22
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:00:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Bruce'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
User entered 'Lisa'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered 'Tracy'	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
Un-reviewed for Safety.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Tracy'	System	12 Oct 2020 14:57:17

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Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Rankin'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
User entered 'Holloway'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered 'Kowalski'	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
Un-reviewed for Safety.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Kowalski'	System	12 Oct 2020 14:57:17

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Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

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Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered '860 Peachwood Ave'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered empty.	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered '860 Peachwood Drive'	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Deland'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered 'Houston'	System	03 Dec 2020 15:03:10
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
	(b) (4)	
User entered empty.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

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Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered empty.	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered 'TX'	System	03 Dec 2020 15:03:10
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
	(b) (4)	
User entered empty.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

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Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered '32720'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered '77081'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:01:03
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered empty.	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered '32720'	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	



**US3222311**

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:01:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered 'US'	System	12 Oct 2020 14:57:55

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Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
User entered '4'	System	03 Dec 2020 15:03:10
User entered '3'	System	11 Nov 2020 17:14:07
User entered '2'	System	02 Nov 2020 19:37:18
User entered '1'	System	12 Oct 2020 14:57:55

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:07:28**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered '03/Dec/2020 10:03'	(b) (4) System	03 Dec 2020 15:03:10

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:07:28

**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)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:03:10

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered		
'USA-US104-2020-MRNA-1273-P301000012'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:10
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Yes (Y)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:55:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:55:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17



**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:55:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Yes (Y)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:55:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:56:22
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 16:00:48
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'No (N)'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Bruce'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
User entered 'Lisa'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered 'Tracy'	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
Un-reviewed for Safety.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
User entered 'BRUCE' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Tracy'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Rankin'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
User entered 'Holloway'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered 'Kowalski'	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
Un-reviewed for Safety.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
User entered 'RANKIN' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 14:57:47
User entered 'Kowalski'	System	12 Oct 2020 14:57:17

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered '860 Peachwood Ave'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered '6550 Mapleridge Street'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:53
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered empty.	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered '860 Peachwood Drive'	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered 'Deland'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered 'Houston'	System	03 Dec 2020 15:03:10
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:55
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
	(b) (4)	
User entered empty.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	



US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered empty.	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered 'TX'	System	03 Dec 2020 15:03:10
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:00:58
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
	(b) (4)	
User entered empty.	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
	(b) (4)	
Signature has been broken.	System	26 Apr 2021 18:19:27
User entered '32720'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
Un-reviewed for Safety.	System	03 Dec 2020 15:03:10
DataPoint Un-verified.	System	03 Dec 2020 15:03:10
User entered '77081'	System	03 Dec 2020 15:03:10
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:13:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 16:01:03
Un-reviewed for Safety.	System	02 Nov 2020 19:37:18
User entered empty.	System	02 Nov 2020 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered '32720'	Jennifer Dittman (b) (4)	16 Oct 2020 16:43:20
	(b) (4)	

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:07:28**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:01:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 19:37:07
User entered 'US'	System	12 Oct 2020 14:57:55

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 16:07:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 18:19:27
User signature succeeded.	Bruce Rankin (b) (4)	20 Feb 2021 14:46:45
	(b) (4)	
User entered '4'	System	03 Dec 2020 15:03:10
User entered '3'	System	11 Nov 2020 17:14:07
User entered '2'	System	02 Nov 2020 19:37:18
User entered '1'	System	12 Oct 2020 14:57:55

**US3222311**

**Folder: SAE USA-US104-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 16:07:28**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
User entered '26/Apr/2021 11:19'	(b) (4) System	26 Apr 2021 18:19:27

US3222311

Folder: SAE USA-US104-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:07:28

**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)
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:13:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:19:27