

US3172211 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:32:11

All time stamps listed in this document are displayed in GMT

US3172211

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

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Participant ID

US3172211

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

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US3172211

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

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

Visit date (dd MMM yyyy)	19 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3172211

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	53
Age Units	YEARS
Age (Derived)	53
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Date of Informed Consent ( <i>dd MMM yyyy</i> )	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

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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) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

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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) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1972
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1972
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 1972
Stop Year (derived)	1972



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	HEARTBURN
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Start Year (derived)	1972
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	OVERWEIGHT
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172211

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1972
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1972
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 1972
Stop Year (derived)	1972

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	LUMBAR HERNIA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	LUMBAR HERNIA SURGERY
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	SENSORY DIABETIC NEUROPATHY
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 (8)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	HYPERTENSION
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 (10)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	RIGHT LEG BLOOD CLOTS
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003



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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	DIABETES TYPE 2
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 (12)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 1983
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1983
Start Year (derived)	1983
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	MUSCLE SPASM BACK
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 (14)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	MUSCLE SPASM LEGS
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 (15)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	INSOMNIA
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 (16)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Condition	CHRONIC BACK PAIN
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: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	19 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:15 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 11:15
Height ( <i>xxx.x</i> )	164.0 cm
Weight ( <i>xxx.x</i> )	92.1 kg
BMI ( <i>xxx.x</i> )	34.24301 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) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

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: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

**Specify**

DIABILITY

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:09:08

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

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

Visit date (dd MMM yyyy)	19 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 105983

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 ☒

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

Height	ND - Not Done
Weight	ND - Not Done

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

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)	19 AUG 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 11:15
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)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

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)	19 AUG 2020
Time of assessment (00:00-23:59)	14:12 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 14:12
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 13:42 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 13:42

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) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

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

Collection date (dd MMM yyyy)	19 AUG 2020
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Collection time (00:00-23:59)	12:58 (24 HR)
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Collection date and time (derived)	19 AUG 2020 12:58
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:46	19 AUG 2020 12:46
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**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

98.4 °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

19 AUG 2020 14:23

PC Open Date & Time

19 AUG 2020 14:02

PC Close Date & Time

19 AUG 2020 16:32

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**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 93.8 °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	19 AUG 2020 21:29
PC Open Date & Time	19 AUG 2020 17:27
PC Close Date & Time	20 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**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

96.0 °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

20 AUG 2020 12:09

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59



US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**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 ☒

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 21 AUG 2020 12:02

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**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

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**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

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

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**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

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**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

19 AUG 2020 14:26

PC Open Date & Time

19 AUG 2020 14:02

PC Close Date & Time

19 AUG 2020 16:32

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**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

19 AUG 2020 21:35

PC Open Date & Time

19 AUG 2020 17:27

PC Close Date & Time

20 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**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

20 AUG 2020 12:11

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59



US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**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

21 AUG 2020 12:01

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**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

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**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 ☐

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

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**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

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**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 ☐

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

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**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 ☐

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 14:27
PC Open Date & Time	19 AUG 2020 14:02
PC Close Date & Time	19 AUG 2020 16:32

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**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 ☐



US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 21:34
PC Open Date & Time	19 AUG 2020 17:27
PC Close Date & Time	20 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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 ☒

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EAB) (1725)

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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 ☒

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:03
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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 ☐

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

Yes ☐

PC Time stamp

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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 ☐



US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

Yes ☐

PC Time stamp

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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 ☐

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

Yes ☐

PC Time stamp

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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

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EAB) (1725)

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

Yes ☐

PC Time stamp

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3172211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3172211

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3172211

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3172211

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

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)	16 SEP 2020
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 09:45
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)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

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)	16 SEP 2020
Time of assessment (00:00-23:59)	12:01 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 12:01
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3172211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3172211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 11:31 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 11:31

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



US3172211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

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

Collection date (dd MMM yyyy)	16 SEP 2020
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Collection time (00:00-23:59)	11:14 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	16 SEP 2020 11:14
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US3172211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:04	16 SEP 2020 11:04
Nasopharyngeal Swab 2	Yes	11:04	16 SEP 2020 11:04

US3172211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**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

98.4 °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

16 SEP 2020 12:15

PC Open Date & Time

16 SEP 2020 11:51

PC Close Date & Time

16 SEP 2020 14:21

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

16 SEP 2020 15:16

PC Close Date & Time

17 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**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

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

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**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

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59



US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**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

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

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**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

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**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

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

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**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

16 SEP 2020 12:15

PC Open Date & Time

16 SEP 2020 11:51

PC Close Date & Time

16 SEP 2020 14:21

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 SEP 2020 15:16

PC Close Date & Time

17 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**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 ☐

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

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**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

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59



US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**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 ☐

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

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**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

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**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 ☐

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

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**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 ☐

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 12:14
PC Open Date & Time	16 SEP 2020 11:51
PC Close Date & Time	16 SEP 2020 14:21

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**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 ☐

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

16 SEP 2020 15:16

PC Close Date & Time

17 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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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US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

Yes ☐

PC Time stamp

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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  
EAB) (1725)

105 of 3162

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

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Yes ☐

PC Time stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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 ☐

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

Yes ☐

PC Time stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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 ☐

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

Yes ☐

PC Time stamp

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**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)

111 of 3162



US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

Yes ☐

PC Time stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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)

113 of 3162

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

Yes ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3172211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3172211

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

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*

US3172211

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3172211

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3172211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 13:25
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)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

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.*

US3172211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

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

Collection date (dd MMM yyyy)	26 OCT 2020
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Collection time (00:00-23:59)	15:08 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	26 OCT 2020 15:08
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US3172211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:09:08

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59



US3172211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 13:49:36

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3172211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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

02 NOV 2020 00:04:53

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3172211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 00:44:47
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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	23 NOV 2020 00:03:44
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 00:18:47

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 11:45:23

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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 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	11 DEC 2020 01:04:07
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 03:06:18

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59



US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 07:59:56

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 17:49:16

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 08:39:06

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 21:37:48

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 09:08:26

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 00:01:27

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 10:54:38

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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

12 FEB 2021 00:07:09

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59



US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 00:01:44
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 16:09:07

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 00:30:36

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 00:03:10

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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

19 MAR 2021 14:39:42

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 00:48:53

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 19:26:14

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 00:30:54

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59



US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 12:07:58

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 18:09:28

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 12:16:56

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 MAY 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2021 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

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03 AUG 2021 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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="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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2021 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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 <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"/>



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 OCT 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	22 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2021 23:59
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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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="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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 DEC 2021 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JAN 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JAN 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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 <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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 MAR 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Open Date & Time](#)

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25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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="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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

22 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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="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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

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23 AUG 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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="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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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"/>

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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[Patient Cloud Close Date & Time](#)

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27 SEP 2022 23:59

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US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**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 ☐



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2022 23:59

US3172211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	21 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59

US3172211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:32:11

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		01 MAR 2021 15:34:26

US3172211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3172211

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3172211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3172211

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3172211

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

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

MISSED, SUBJECT ON OPEN  
LABEL.

If Contact Not Made, please provide Comments

US3172211

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

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

Visit date (dd MMM yyyy)	12 APR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3172211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 APR 2021
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	12 APR 2021 12:06
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)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3172211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 APR 2021

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

US3172211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

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

Collection date (dd MMM yyyy)	12 APR 2021
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Collection time (00:00-23:59)	13:22 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	12 APR 2021 13:22
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US3172211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3172211**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

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*

**US3172211**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

Date of Contact	28 SEP 2020
Time of Contact	11:54
Date and Time of Contact (derived)	28 SEP 2020 11:54
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

Symptom Day

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

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

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

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

Symptom Day

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

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	26 SEP 2020
------	-------------

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

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

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

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

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

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

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

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

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

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

Symptom Day

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

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	27 SEP 2020
------	-------------

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

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

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

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

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

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

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

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

Symptom Day

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	28 SEP 2020
------	-------------

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

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

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

Temperature	37.1 C
-------------	--------

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

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

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

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

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

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

Symptom Day

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

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 SEP 2020
------	-------------

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

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

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

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

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

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

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

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

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

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

Date of Visit	28 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	28 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3172211

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 17 Feb 2021 13:08:30

Generated On: 09 Jun 2021 15:32:11

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	30 SEP 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3172211

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3172211

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:09:07

Generated On: 09 Jun 2021 15:32:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	11:59 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 11:59
Height (xxx.x)	164.9 cm
Weight (xxx.x)	092.9 kg
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)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172211

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:08:30

Generated On: 09 Jun 2021 15:32:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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



US3172211

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 17 Feb 2021 13:08:30

Generated On: 09 Jun 2021 15:32:11

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 SEP 2020

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID SICKD28

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

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) \_\_\_\_\_

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

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.*

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3172211

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

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

Was this visit performed? Yes ☒  
No ☐

Visit date (dd MMM yyyy) 22 FEB 2021

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

Folder OID UNBLND\_DECIDE

US3172211

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Date of updated informed consent (dd MMM yyyy)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <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 (dd MMM yyyy)	09 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3172211

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

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



US3172211

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 14:40
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)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3172211

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	16:19 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 16:19
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)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3172211

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

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 FEB 2021

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

US3172211

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

Form: Exposure

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

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) 22 FEB 2021

What was the treatment time? (00:00-23:59) 15:49 (24 HR)

Treatment Date and Time (derived) 22 FEB 2021 15:49

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

US3172211

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 22 FEB 2021

Collection time (00:00-23:59) 15:18 (24 HR)

Collection date and time (derived) 22 FEB 2021 15:18

US3172211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 FEB 2021
Collection time (00:00 - 23:59)	15:19
Collection Date and Time (derived)	22 FEB 2021 15:19

US3172211

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

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*



US3172211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 13:54:31

Generated On: 09 Jun 2021 15:32:11

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

US3172211

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

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

Visit date (dd MMM yyyy)	22 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	OLD29
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US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

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)	22 MAR 2021
Time of assessment (00:00-23:59)	11:37 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 11:37
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

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)	22 MAR 2021
Time of assessment (00:00-23:59)	14:25 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 14:25
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3172211

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3172211

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

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) 22 MAR 2021

What was the treatment time? (00:00-23:59) 13:55 (24 HR)

Treatment Date and Time (derived) 22 MAR 2021 13:55

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

US3172211

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*



US3172211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172211

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

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

Visit date (dd MMM yyyy)	12 APR 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	OLD57
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US3172211

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 APR 2021
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	12 APR 2021 12:06
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)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172211

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 APR 2021

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

US3172211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

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

Collection date (dd MMM yyyy)	12 APR 2021
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Collection time (00:00-23:59)	13:22 (24 HR)
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Collection date and time (derived)	12 APR 2021 13:22
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US3172211

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

AEID	
Adverse event	RIB CAGE ARTHRALGIA (LEFT SIDED)
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)	25 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)	10 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

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



US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

AEID	
Adverse event	INFLUENZA B
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)	25 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)	5 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

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 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 _____	
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 (4)

Generated On: 09 Jun 2021 15:32:11

AEID

Adverse event

LEFT KIDNEY STONE  
EXACERBATION

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)

7 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

AEID	USA-US118-2021-MRNA-1273-P30 1000015
Adverse event	WORSENING BACK MUSCLE SPASM
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 APR 2021
Hospital Discharge Date (dd MMM yyyy)	11 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

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SUBJECT WITH HISTORY OF  
BACK MUSCLE SPASM SINCE  
2018 WITH NO SYMPTOMS  
UNTIL 10APR2021 WHEN HE  
STARTED WITH THE PAIN. HE  
WENT TO DOCTOR HOSPITAL  
ON THIS DAY MENTIONED AT  
5:00 AM ER FOR BETTER  
EVALUATION AND  
TREATMENT. HE WAS  
ADMITTED AT ER FROM 5:00  
AM UNTIL 11APR2021 14:00,  
WHERE HE WAS DISCHARGED  
HOME WITH TREATMENT.  
TODAY HE IS HERE ONSITE FOR  
VISIT DAY 57 AND 209 AS PER  
PROTOCOL. SUBJECT  
REPORTED FEELING BETTER  
BUT CONTINUED WITH  
TREATMENT. NO OTHER  
COMPLAINT REPORTED. WE  
REQUESTED MEDICAL  
RECORDS AND WILL  
CONTINUE MONITORING  
SUBJECT BY PHONE CALL  
UNTIL MEDICAL RECORDS ARE  
RECEIVED. SARS-COV-2  
(COVID-19) 10APR2021  
RESULTS- NEGATIVE.  
10APR32021 LUMBAR SPINE CT  
INTERP RECON IMPRESSION: 1.  
POSTERIOR INSTRUMENTED  
FUSION L5-S1. 2. MILD  
DEGENARTIVE CHANGES AT  
L4-L5. 3. NO ACUTE FRACTURE  
OR DISLOCATION. 4. IVC  
FILTER. FEW OF THE LIMBS OF

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

---

THE FILTER ARE OUTSIDE OF  
THE CONFINES OF THE IVC  
LUMEN. NONEMERGENT  
EVALUATION BY  
INTERVENTIONAL RADIOLOGY  
IS RECOMMENDED. 10APR2021  
ABD PEL CT WO IV WO PO CON  
IMPRESSION: POSTSURGICAL  
CHANGES, BUT NO ACUTE  
FINDINGS IN THE ABDOMEN OR  
PELVIS.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

AEID	USA-US118-2021-MRNA-1273-P30 1000015
Adverse event	ACUTE EXACERBATION OF ABDOMINAL PAIN
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)	08 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 APR 2021
Hospital Discharge Date (dd MMM yyyy)	11 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

AFTER MEDICAL RECORDS  
RECEIVED AND REVIEWED A  
NEW SAE WORSENERED AND  
WILL BE REPORTED TO THE  
SPONSOR. THIS SAE IS MOST  
LIKELY RELATED TO PAST  
MEDICAL HISTORY OF  
CHRONIC GASTRITIS. SUBJECT  
WAS ADMITTED AND  
TREATMENT AT  
DOCTOR/HOSPITAL FROM  
10APR2021 AND DISCHARGED  
ON 11APR2021. MEDICAL  
HISTORY AND MEDICATION  
LOG WERE  
UPDATED.SARS-COV-2  
(COVID-19) 10APR2021  
RESULTS- NEGATIVE.  
10APR32021 LUMBAR SPINE CT  
INTERP RECON IMPRESSION: 1.  
POSTERIOR INSTRUMENTED  
FUSION L5-S1. 2. MILD  
DEGENARTIVE CHANGES AT  
L4-L5. 3. NO ACUTE FRACTURE  
OR DISLOCATION. 4. IVC  
FILTER. FEW OF THE LIMBS OF  
THE FILTER ARE OUTSIDE OF  
THE CONFINES OF THE IVC  
LUMEN. NONEMERGENT  
EVALUATION BY  
INTERVENTIONAL RADIOLOGY  
IS RECOMMENDED. 10APR2021  
ABD PEL CT WO IV WO PO CON  
IMPRESSION: POSTSURGICAL  
CHANGES, BUT NO ACUTE  
FINDINGS IN THE ABDOMEN OR  
PELVIS.

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

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 13:08:29

Generated On: 09 Jun 2021 15:32:11

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

Yes ☒

No ☐

---

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

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US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication HEARTBURN

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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US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 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 (2)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication EXCEDRIN (ACETAMINOPHEN  
250MG, ASPIRIN 250MG,  
CAFFEINE 65MG)

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE (SECONDARY TO  
INFLUENZA B INFECTION)

Dose per administration 250/250/65

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Transdermal	<input type="checkbox"/>
	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)	25 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)	25 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 (3)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication MYALGIA, ARTHRALGIA,  
HEADACHES - (NO SAR OR  
MAAE)

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	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)	25 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)	28 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 (4)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication ARTHRALGIA (RIB CAGE)

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 (4)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 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) 28 SEP 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 (5)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication VITAMIN C OVER THE COUNTER

Prophylaxis Yes ☐  
No ☒

Indication FATIGUE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	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)	29 SEP 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 checked="" type="radio"/>
	No	<input 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) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication VITAMIN D OVER THE COUNTER

Prophylaxis Yes ☐  
No ☒

Indication FATIGUE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	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)	29 SEP 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 checked="" type="radio"/>
	No	<input 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) 22 Apr 2021 16:25:02

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication INFLUENZA B

Dose per administration 1000

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) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	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) 3 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication OSELTAMIVIR

Prophylaxis Yes ☐  
No ☒

Indication INFLUENZA B

Dose per administration 75

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) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	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) 3 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 (9)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication SCHIZOPHRENIA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 APR 2021
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	803 <input type="radio"/>
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☒  
No ☐

Indication CARDIOVASCULAR  
PROPHYLAXIS

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 22 Apr 2021 16:25:02

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Name of Medication JANUMET

Prophylaxis Yes ☐  
No ☒

Indication DIABETES MELLITUS TYPE 2

Dose per administration 50/500

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication MEDROL DOSE PACK

Prophylaxis Yes ☐  
No ☒

Indication INFLUENZA B

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

AS DIRECTED TIMES 5 DAYS

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) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	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) 3 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 (13)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication RIPERIDONE

Prophylaxis Yes ☐  
No ☒

Indication SCHIZOPHRENIA

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 APR 2021	
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 (14)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication TEMAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐  
No ☒

Indication HEARTBURN

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 (15)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN MAR 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 (16)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication HEARTBURN

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 (16)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	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 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 (17)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

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 (17)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (18)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐  
No ☒

Indication WORSENING CHRONIC LOWER  
BACK PAIN

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (19)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication AMANTADINE

Prophylaxis Yes ☒  
No ☐

Indication ANTIVIRAL INFLUENZA  
PREVENTIVE

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 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 (20)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 16:25:02

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication DONEPEZIL

Prophylaxis Yes ☐  
No ☒

Indication MILD MEMORY LOSS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication RISPERDAL

Prophylaxis Yes ☐  
No ☒

Indication SCHIZOPHRENIA

Dose per administration 2

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 (22)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 16:25:02

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Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETES NEUROPATHY

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 (23)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (24)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication WORSENING CHRONIC LOWER  
BACK PAIN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication DIVALPROEX

Prophylaxis Yes ☐  
No ☒

Indication SCHIZOPHRENIA

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 (25)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (26)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication ADDERALL XR

Prophylaxis Yes ☐  
No ☒

Indication ATTENTION DEFICIT  
HYPERACTIVE DISORDER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 16:25:02

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2010	
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 (27)

Data signed: (b) (4) 22 Apr 2021 16:25:02

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Name of Medication SUCRALFATE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (28)

Data signed: (b) (4) 22 Apr 2021 16:25:02

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Name of Medication ALBUTEROL 2.5MG

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 1.25/3

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1980	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
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 (29)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication ARFORMOTEROL

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1980	
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 (30)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication BUDESONIDE 0.5MG

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 0.5/2

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1980	
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 (31)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication DICLOFENAC

Prophylaxis Yes ☐  
No ☒

Indication WORSENING CHRONIC LOWER  
BACK PAIN

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)		10 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 APR 2021
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 (33)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 22 Apr 2021 16:25:02

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	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 APR 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 (34)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication ERGOCALCIFEROL

Prophylaxis Yes ☐  
No ☒

Indication VITAMIN DEFICIENCY

Dose per administration 50000

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 (34)

Data signed: (b) (4) 22 Apr 2021 16:25:02

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	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)	12 OCT 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 checked="" type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

Name of Medication GLIMEPIRIDE

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE 2

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 (35)

Data signed: (b) (4) 22 Apr 2021 16:25:02

Generated On: 09 Jun 2021 15:32:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 22 Apr 2021 16:25:02

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Name of Medication SYMBICORT (PUFF)

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 160/45

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 22 Apr 2021 16:25:02

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1980	
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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Data signed: (b) (4) 22 Apr 2021 16:25:02

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Name of Medication HUMALOG SLIDING SCALE-  
20-130- 0 UNITS, 131-180- 2  
UNITS, 181-240- 4 UNITS,  
241-300- 6 UNITS, 301-350- 8  
UNITS, 351-400- 10 UNITS,  
>400-12 UNITS

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE 2

Dose per administration 1000

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

If dose unit is Other, specify UNITS/ML

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 ☐

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	Topical	<input type="checkbox"/>
	Subcutaneous	<input checked="" type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 APR 2021	
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"/>

US3172211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3172211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 APR 2021	ABD PEL CT WO IV WO PO CON	Adverse Event	
10 APR 2021	LUMBAR SPINE CT INTERP RECON	Adverse Event	



US3172211

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:32:11

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

US3172211

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:32:11

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 ☐

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

SAEID	USA-US118-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

SAEID	USA-US118-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	13/APR/2021 18:23
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

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

SAEID	USA-US118-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/APR/2021 14:28
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.	True

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

SAEID	USA-US118-2021-MRNA-1273-P301000015
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/APR/2021 11:35
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

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000017

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

SAEID	USA-US118-2021-MRNA-1273-P301000017
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 16:25:03

Generated On: 09 Jun 2021 15:32:11

SAEID	USA-US118-2021-MRNA-1273-P301000017
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	16/APR/2021 14:16
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

US3172211 (Prod: Suncoast Research Group LLC - ERN-PPDS)

**US3172211**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:32:11**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'US3172211'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 16:35:44

US3172211

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:31:05

US3172211

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 16:35:45

US3172211

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4)	19 Aug 2020 18:31:05
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'SCRN'	System	19 Aug 2020 18:31:05

US3172211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered (b) (6) 1966'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 16:35:46

US3172211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '53'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:32:54



**US3172211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:32:11**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'YEARS'	System	19 Aug 2020 18:32:54

US3172211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '53'	System	19 Aug 2020 17:51:07

US3172211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:11

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'Male (M)'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:54
	(b) (4)	

US3172211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:54
	(b) (4)	

US3172211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:11

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'I'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:54
	(b) (4)	

US3172211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:54
	(b) (4)	

US3172211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:32:54

**US3172211**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:32:11**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:54
	(b) (4)	



US3172211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:54
	(b) (4)	

US3172211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:54
	(b) (4)	

US3172211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Aug 2020 18:32:54
	(b) (4)	

US3172211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:11

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:54
	(b) (4)	

US3172211

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:11

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:54
	(b) (4)	

US3172211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '19 Aug 2020'	Mariete Rendon (b) (4)	19 Aug 2020 17:51:07
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Aug 2020'	System	19 Aug 2020 17:51:07

**US3172211**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '2020'	System	19 Aug 2020 17:51:07



US3172211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'Amendment 1 (1)' reason for change:	Mariete Rendon (b) (4)	17 Sep 2020 18:58:28
Data Entry Error	(b) (4)	
User entered 'Amendment 2 (2)'	Mariete Rendon (b) (4)	19 Aug 2020 17:51:07
	(b) (4)	

US3172211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 17:51:07

US3172211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:11

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Aug 2020 17:51:07
	(b) (4)	

US3172211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Aug 2020 17:51:07
	(b) (4)	

US3172211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 17:51:07

US3172211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 16:35:45

US3172211

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'I'	System	19 Aug 2020 17:51:13

US3172211

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	19 Aug 2020 17:51:13
	(b) (4)	



US3172211

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:32:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:58

US3172211

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:42:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:42:31
Data point term sent to Coder	System	19 Aug 2020 18:41:26
User entered 'TONSILLITIS'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:41:10

**US3172211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'UN UNK 1972'	Mariete Rendon (b) (4)	19 Aug 2020 18:41:10
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:41:10
	(b) (4)	

US3172211

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User closed query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of TONSILLECTOMY was performed in 1972. Please review and update if appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of TONSILLECTOMY was performed in 1972. Please review and update if appropriate. Otherwise, clarify.' answered with 'Data was updated' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 02:13:30
Query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of TONSILLECTOMY was performed in 1972. Please review and update if appropriate. Otherwise, clarify.' answered with 'Data was updated' (Site from DM).	Jessie Downs (b) (4) (b) (4)	10 Sep 2020 18:11:16
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	10 Sep 2020 18:10:50
User opened query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of TONSILLECTOMY was performed in 1972. Please review and update if appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 12:39:19
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 18:41:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 18:41:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:41:35
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 18:41:10
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:41:10

US3172211

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'UN UNK 1972' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	10 Sep 2020 18:10:50
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:41:10

**US3172211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:41:10
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 1972'	System	19 Aug 2020 18:41:10



**US3172211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '1972'	System	19 Aug 2020 18:41:10

**US3172211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 1972'	System	10 Sep 2020 18:10:50
User entered empty.	System	19 Aug 2020 18:41:10

**US3172211**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '1972'	System	10 Sep 2020 18:10:50
User entered empty.	System	19 Aug 2020 18:41:10

US3172211

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:43:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:43:34
Data point term sent to Coder	System	19 Aug 2020 18:42:27
User entered 'HEARTBURN'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:41:29

US3172211

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'UN UNK 1972' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:07:36
User entered 'UN Feb 2020'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:41:29

**US3172211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:41:29
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	19 Aug 2020 18:41:29
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Aug 2020 18:41:29
	(b) (4)	



**US3172211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:41:29
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 1972'	System	30 Sep 2020 16:07:36
User entered 'Feb 2020'	System	19 Aug 2020 18:41:29

**US3172211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '1972'	System	30 Sep 2020 16:07:36
User entered '2020'	System	19 Aug 2020 18:41:29

**US3172211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	19 Aug 2020 18:41:29

**US3172211**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	19 Aug 2020 18:41:29

US3172211

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Overweight, LLT: Overweight - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:43:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:43:34
Data point term sent to Coder	System	19 Aug 2020 18:42:27
User entered 'OVERWEIGHT'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:42:04

**US3172211**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'UN UNK 2005'	Mariete Rendon (b) (4)	19 Aug 2020 18:42:04
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:42:04



**US3172211**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:42:04

**US3172211**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Aug 2020 18:42:04
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:42:04
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 2005'	System	19 Aug 2020 18:42:04

**US3172211**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '2005'	System	19 Aug 2020 18:42:04

**US3172211**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	19 Aug 2020 18:42:04

**US3172211**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	19 Aug 2020 18:42:04

US3172211

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:43:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:43:34
Data point term sent to Coder	System	19 Aug 2020 18:42:30
User entered 'TONSILLECTOMY'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:42:28



US3172211

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'UN UNK 1972'	Mariete Rendon (b) (4)	19 Aug 2020 18:42:28
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:42:28
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Aug 2020 18:42:28
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'UN UNK 1972'	Mariete Rendon (b) (4)	19 Aug 2020 18:42:28
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:42:28
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 1972'	System	19 Aug 2020 18:42:28

**US3172211**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '1972'	System	19 Aug 2020 18:42:28

**US3172211**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 1972'	System	19 Aug 2020 18:42:28



**US3172211**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '1972'	System	19 Aug 2020 18:42:28

US3172211

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Lumbar hernia, LLT: Lumbar hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:44:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:44:21
Data point term sent to Coder	System	19 Aug 2020 18:43:31
User entered 'LUMBAR HERNIA'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:43:17

US3172211

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'UN UNK 2005'	Mariete Rendon (b) (4)	19 Aug 2020 18:43:17
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:43:17
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Aug 2020 18:43:17
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'UN UNK 2008'	Mariete Rendon (b) (4)	19 Aug 2020 18:43:17
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:43:17
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 2005'	System	19 Aug 2020 18:43:17



**US3172211**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '2005'	System	19 Aug 2020 18:43:17

**US3172211**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 2008'	System	19 Aug 2020 18:43:17

**US3172211**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '2008'	System	19 Aug 2020 18:43:17

US3172211

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Intervertebral disc operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 13:55:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 13:55:34
Data point term sent to Coder	System	19 Aug 2020 18:44:33
User entered 'LUMBAR HERNIA SURGERY'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:43:38

US3172211

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'UN UNK 2008'	Mariete Rendon (b) (4)	19 Aug 2020 18:43:38
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:43:38
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Aug 2020 18:43:38
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'UN UNK 2008'	Mariete Rendon (b) (4)	19 Aug 2020 18:43:38
	(b) (4)	



**US3172211**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:43:38
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 2008'	System	19 Aug 2020 18:43:38

**US3172211**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '2008'	System	19 Aug 2020 18:43:38

**US3172211**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 2008'	System	19 Aug 2020 18:43:38

**US3172211**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '2008'	System	19 Aug 2020 18:43:38

US3172211

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:32:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:08:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 20:08:52
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:29:55
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:20:09
Data point term sent to Coder	System	28 Oct 2020 21:19:58
Coding entries removed.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:19:48
User entered 'SENSORY DIABETIC NEUROPATHY' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:19:48
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 07:07:41
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:05:47

US3172211

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:32:11

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	30 Sep 2020 16:05:47
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:04:45
User entered 'diabetic neuropathy'	Mariete Rendon (b) (4)	30 Sep 2020 16:04:00
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'un UNK 2018'	Mariete Rendon (b) (4)	30 Sep 2020 16:04:00
	(b) (4)	



**US3172211**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:04:00
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:32:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:04:00

**US3172211**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:04:00
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:32:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:04:00
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 2018'	System	30 Sep 2020 16:04:00

**US3172211**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '2018'	System	30 Sep 2020 16:04:00

**US3172211**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	30 Sep 2020 16:04:00

**US3172211**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	30 Sep 2020 16:04:00



US3172211

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:32:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:30:17
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'No complaint from subject. Subject does not take any medication.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:21:32
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 07:08:31
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:08:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:08:57
Data point term sent to Coder	System	30 Sep 2020 16:07:48
User entered 'hypertension'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:07:06

US3172211

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'un UNK 2018'	Mariete Rendon (b) (4)	30 Sep 2020 16:07:06
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:07:06

**US3172211**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:32:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:07:06

**US3172211**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:07:06
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:32:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:07:06
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 2018'	System	30 Sep 2020 16:07:06

**US3172211**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '2018'	System	30 Sep 2020 16:07:06



**US3172211**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	30 Sep 2020 16:07:06

**US3172211**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	30 Sep 2020 16:07:06

US3172211

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:32:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Thrombosis, LLT: Clot blood - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 08:18:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Oct 2020 08:18:13
Data point term sent to Coder	System	30 Sep 2020 16:09:52
User entered 'right leg blood clots'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:09:00

US3172211

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'un UNK 1998'	Mariete Rendon (b) (4)	30 Sep 2020 16:09:00
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:09:00
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:32:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	30 Sep 2020 16:09:00
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'un UNK 2003'	Mariete Rendon (b) (4)	30 Sep 2020 16:09:00
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:32:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:09:00
	(b) (4)	



**US3172211**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 1998'	System	30 Sep 2020 16:09:00

**US3172211**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '1998'	System	30 Sep 2020 16:09:00

**US3172211**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 2003'	System	30 Sep 2020 16:09:00

**US3172211**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '2003'	System	30 Sep 2020 16:09:00

US3172211

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:32:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:10:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:10:55
Data point term sent to Coder	System	30 Sep 2020 16:09:52
User entered 'diabetes type 2'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:09:35

US3172211

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'un UNK 2018'	Mariete Rendon (b) (4)	30 Sep 2020 16:09:35
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:09:35
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:32:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	30 Sep 2020 16:09:35
	(b) (4)	



**US3172211**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:09:35
	(b) (4)	

US3172211

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:32:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:09:35
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 2018'	System	30 Sep 2020 16:09:35

**US3172211**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '2018'	System	30 Sep 2020 16:09:35

**US3172211**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	30 Sep 2020 16:09:35

**US3172211**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	30 Sep 2020 16:09:35

US3172211

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:32:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:11:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:11:52
Data point term sent to Coder	System	30 Sep 2020 16:10:53
User entered 'kidney stones'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:10:14

**US3172211**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'un UNK 1983'	Mariete Rendon (b) (4)	30 Sep 2020 16:10:14
	(b) (4)	



**US3172211**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:10:14

US3172211

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:32:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:50:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:10:14

US3172211

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 15:50:52
	(b) (4)	
User entered 'un UNK 2017'	Mariete Rendon (b) (4)	30 Sep 2020 16:10:14
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:32:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:10:14
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 1983'	System	30 Sep 2020 16:10:14

**US3172211**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '1983'	System	30 Sep 2020 16:10:14

**US3172211**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	14 Oct 2020 15:50:52
User entered 'Jan 2017'	System	30 Sep 2020 16:10:14

**US3172211**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	14 Oct 2020 15:50:52
User entered '2017'	System	30 Sep 2020 16:10:14



US3172211

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:32:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
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: Back muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:11:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:11:51
Data point term sent to Coder	System	30 Sep 2020 16:10:57
User entered 'muscle spasm back'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:10:42

US3172211

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'un UNK 2018'	Mariete Rendon (b) (4)	30 Sep 2020 16:10:42
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:10:42
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:32:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:10:42

**US3172211**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:10:42
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:32:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:10:42
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 2018'	System	30 Sep 2020 16:10:42

**US3172211**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '2018'	System	30 Sep 2020 16:10:42



**US3172211**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	30 Sep 2020 16:10:42

**US3172211**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	30 Sep 2020 16:10:42

US3172211

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:32:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
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 spasm - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 09:13:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 09:13:12
Data point term sent to Coder	System	30 Sep 2020 16:11:58
User entered 'muscle spasm legs'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:11:15

US3172211

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'un UNK 2018'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:11:15

**US3172211**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:11:15
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:32:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	30 Sep 2020 16:11:15
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:11:15
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:32:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:11:15
	(b) (4)	



**US3172211**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 2018'	System	30 Sep 2020 16:11:15

**US3172211**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '2018'	System	30 Sep 2020 16:11:15

**US3172211**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	30 Sep 2020 16:11:15

**US3172211**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	30 Sep 2020 16:11:15

US3172211

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:32:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:12:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:12:57
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:11:59
User entered 'insomnia'	Mariete Rendon (b) (4)	30 Sep 2020 16:11:31
	(b) (4)	

US3172211

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'un UNK 2010'	Mariete Rendon (b) (4)	30 Sep 2020 16:11:31
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:11:31
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:32:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	30 Sep 2020 16:11:31
	(b) (4)	



**US3172211**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:11:31
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:32:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:11:31
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 2010'	System	30 Sep 2020 16:11:31

**US3172211**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '2010'	System	30 Sep 2020 16:11:31

**US3172211**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	30 Sep 2020 16:11:31

**US3172211**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	30 Sep 2020 16:11:31

US3172211

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:32:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Schizophrenia and other psychotic disorders, HLT: Schizophrenia NEC, PT: Schizophrenia, LLT: Schizophrenia - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:15:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:15:04
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:14:03
User entered 'schizophrenia'	Mariete Rendon (b) (4)	30 Sep 2020 16:13:52
	(b) (4)	

US3172211

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'un UNK 1975'	Mariete Rendon (b) (4)	30 Sep 2020 16:13:52
	(b) (4)	



**US3172211**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:13:52

**US3172211**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:32:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	30 Sep 2020 16:13:52
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:13:52
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:32:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:13:52
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 1975'	System	30 Sep 2020 16:13:52

**US3172211**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '1975'	System	30 Sep 2020 16:13:52

**US3172211**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	30 Sep 2020 16:13:52

**US3172211**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	30 Sep 2020 16:13:52



US3172211

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:32:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 19:14:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Apr 2021 19:14:11
Data point term sent to Coder	System	15 Apr 2021 19:13:22
User entered 'chronic back pain'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:13:21

US3172211

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'un UNK 2018'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:13:21

**US3172211**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:13:21

**US3172211**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:32:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:13:21

**US3172211**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:13:21

US3172211

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:32:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:13:21

**US3172211**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'Jan 2018'	System	15 Apr 2021 19:13:21

**US3172211**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '2018'	System	15 Apr 2021 19:13:21



**US3172211**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	15 Apr 2021 19:13:21

**US3172211**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	15 Apr 2021 19:13:21

US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:33:48

US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '19 Aug 2020'	Mariete Rendon (b) (4)	19 Aug 2020 18:33:48
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '11:15'	Mariete Rendon (b) (4)	19 Aug 2020 18:33:48
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '19 Aug 2020 11:15'	System	19 Aug 2020 18:33:48

US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '164.0' cm	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:33:48
DataPoint set to visible.	System	19 Aug 2020 17:51:13

US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '92.1' kg	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:33:48
DataPoint set to visible.	System	19 Aug 2020 17:51:13



US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
Amendment Manager: User entered '34.24301'	System	17 Sep 2020 00:14:12
User entered '34.2'	System	19 Aug 2020 18:33:48
DataPoint set to visible.	System	19 Aug 2020 17:51:13

**US3172211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'kg/m2'	System	19 Aug 2020 18:33:48
DataPoint set to visible.	System	19 Aug 2020 17:51:13

US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered missing code ND - Not Done.	Mariete Rendon (b) (4)	19 Aug 2020 18:33:48
	(b) (4)	

US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 06:42:13
Query 'Data is required. Please provide.' answered with 'Per Guidelines, ND' (Site from System).	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 21:22:52
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 18:33:48
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:33:48

US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Aug 2020 18:33:48
	(b) (4)	

**US3172211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:33:48

**US3172211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'bpm'	System	19 Aug 2020 18:33:48

US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:33:48



US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'breaths/min'	System	19 Aug 2020 18:33:48

US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:33:48

US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'mmHg'	System	19 Aug 2020 18:33:48

US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:33:48

**US3172211**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'mmHg'	System	19 Aug 2020 18:33:48

US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42

US3172211

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42

US3172211

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	28 Sep 2020 21:29:08
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	19 Aug 2020 18:38:57
	(b) (4)	



US3172211

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	28 Sep 2020 21:29:08
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	28 Sep 2020 21:29:08
	(b) (4)	
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 15:40:32
User entered '19 Aug 2020'	Mariete Rendon (b) (4)	19 Aug 2020 18:38:57
	(b) (4)	

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

**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 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

**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 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

**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 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:32:00

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

**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 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

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 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

[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 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:32:00

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

**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 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:32:00



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

**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 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

[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 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:32:00

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

**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 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:32:00

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

**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 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'DIABILITY'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	



US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

**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 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:32:00

US3172211

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:11

**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 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'I'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	

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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 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Aug 2020 18:32:00
	(b) (4)	

US3172211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:43:53

US3172211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '19 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:43:53



US3172211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4)	19 Aug 2020 18:43:53
	(b) (4)	

**US3172211**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'VISIT1'	System	19 Aug 2020 18:43:53

US3172211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 16:35:47

US3172211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:11

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:35:46
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:35:46
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 16:35:47
User entered '105983' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 16:35:47

US3172211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:11

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 16:35:47

US3172211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:11

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)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:05

**US3172211**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:32:11**

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)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:05

US3172211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:11

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:05



US3172211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:11

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:05

US3172211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:05

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '19 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '11:15'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered '19 Aug 2020 11:15'	System	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '36.9' C	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '89'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'bpm'	System	19 Aug 2020 18:39:45



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '16'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'breaths/min'	System	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '139'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'mmHg'	System	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '80'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'mmHg'	System	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45



US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:17:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 21:17:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	19 Aug 2020 21:17:15
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 18:39:45
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '19 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	19 Aug 2020 21:17:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 05:35:44
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		19 Aug 2020 21:17:15
User entered '14:12' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	19 Aug 2020 21:17:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

**US3172211**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered '19 Aug 2020 14:12'	System	19 Aug 2020 21:17:15
User entered empty.	System	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '36.9' C reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	19 Aug 2020 21:17:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	19 Aug 2020 21:17:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '71' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	19 Aug 2020 21:17:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'bpm'	System	19 Aug 2020 21:17:15
User entered empty.	System	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '14' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	19 Aug 2020 21:17:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'breaths/min'	System	19 Aug 2020 21:17:15
User entered empty.	System	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '131' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	19 Aug 2020 21:17:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'mmHg'	System	19 Aug 2020 21:17:15
User entered empty.	System	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '89' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	19 Aug 2020 21:17:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:39:45

US3172211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'mmHg'	System	19 Aug 2020 21:17:15
User entered empty.	System	19 Aug 2020 18:39:45



US3172211

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Sep 2020 21:28:54
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:12

US3172211

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '19 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Sep 2020 21:28:54
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:12

US3172211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 17:51:36

US3172211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 17:51:36

US3172211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

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)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 17:51:36

US3172211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 17:51:36

US3172211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '19 Aug 2020'	Mariete Rendon (b) (4)	19 Aug 2020 17:51:36
	(b) (4)	

US3172211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '13:42'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 17:51:36



US3172211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered '19 Aug 2020 13:42'	System	19 Aug 2020 17:51:36

US3172211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Left Arm (LEFT ARM)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 17:51:36

US3172211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'ONCE'	System	19 Aug 2020 17:51:36

US3172211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 17:51:36

US3172211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:25

US3172211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '19 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:25

US3172211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '12:58'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:25

**US3172211**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:32:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered '19 Aug 2020 12:58'	System	19 Aug 2020 18:45:25



US3172211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:32:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '19 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:56

**US3172211**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:56

US3172211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:56

**US3172211**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:32:11**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '12:46'	Mariete Rendon (b) (4)	19 Aug 2020 18:45:56
	(b) (4)	

**US3172211**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered '19 Aug 2020 12:46'	System	19 Aug 2020 18:45:56

US3172211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:56

US3172211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 13:31:51
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:56

US3172211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 13:31:51
User entered '12:46'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:45:56



**US3172211**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered empty.	System	17 Sep 2020 13:31:51
User entered '19 Aug 2020 12:46'	System	19 Aug 2020 18:45:56

US3172211

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	19 Aug 2020 21:17:45

**US3172211**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'I'	System	19 Aug 2020 21:17:45

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:22:31', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c4a01242-2176-48c4-8ccf-c64f323f34b9'	System	19 Aug 2020 18:23:41
User entered 'Yes (Y)'	System	19 Aug 2020 18:23:41

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:23:05', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c4a01242-2176-48c4-8ccf-c64f323f34b9' User entered '98.4'	System	19 Aug 2020 18:23:41
	System	19 Aug 2020 18:23:41

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:23:16', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c4a01242-2176-48c4-8ccf-c64f323f34b9'	System	19 Aug 2020 18:23:41
User entered 'No (N)'	System	19 Aug 2020 18:23:41

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:23:37', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c4a01242-2176-48c4-8ccf-c64f323f34b9' User entered '19 Aug 2020 14:23'	System	19 Aug 2020 18:23:41
	System	19 Aug 2020 18:23:41



US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Aug 2020 14:02'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Aug 2020 16:32'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:27:59', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57fd6969-26dd-4e43-9867-2923566b019a' User entered 'Yes (Y)'	System	20 Aug 2020 01:29:52
	System	20 Aug 2020 01:29:52

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:28:27', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57fd6969-26dd-4e43-9867-2923566b019a' User entered '93.8'	System	20 Aug 2020 01:29:52
	System	20 Aug 2020 01:29:52

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:28:40', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57fd6969-26dd-4e43-9867-2923566b019a'	System	20 Aug 2020 01:29:52
User entered 'No (N)'	System	20 Aug 2020 01:29:52

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:29:47', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57fd6969-26dd-4e43-9867-2923566b019a' User entered '19 Aug 2020 21:29'	System	20 Aug 2020 01:29:52
	System	20 Aug 2020 01:29:52

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Aug 2020 17:27'	System	19 Aug 2020 17:51:36



US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 2'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:08:23', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '1018ad3e-0701-487e-b2d1-7338e8481514' User entered 'Yes (Y)'	System	20 Aug 2020 16:09:37
	System	20 Aug 2020 16:09:37

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:08:50', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '1018ad3e-0701-487e-b2d1-7338e8481514' User entered '96.0'	System	20 Aug 2020 16:09:37
	System	20 Aug 2020 16:09:37

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:09:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '1018ad3e-0701-487e-b2d1-7338e8481514'	System	20 Aug 2020 16:09:37
User entered 'No (N)'	System	20 Aug 2020 16:09:37

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:09:32', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '1018ad3e-0701-487e-b2d1-7338e8481514' User entered '20 Aug 2020 12:09'	System	20 Aug 2020 16:09:37
	System	20 Aug 2020 16:09:37

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 17:51:36



US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 3'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:01:50', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '511f888d-0049-49ac-97f5-eb37134cf11a' User entered 'No (N)'	System	21 Aug 2020 16:02:12
	System	21 Aug 2020 16:02:12

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:01:56', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '511f888d-0049-49ac-97f5-eb37134cf11a'	System	21 Aug 2020 16:02:12
User entered 'No (N)'	System	21 Aug 2020 16:02:12

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:02:04', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '511f888d-0049-49ac-97f5-eb37134cf11a' User entered '21 Aug 2020 12:02'	System	21 Aug 2020 16:02:12
	System	21 Aug 2020 16:02:12

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 4'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 5'	System	19 Aug 2020 17:51:36



US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 17:51:36



US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 6'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 17:51:36



US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 7'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:26:32', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '26c99f1a-42ba-4605-bdca-4249656a2150' User entered 'None (1)'	System	19 Aug 2020 18:26:41
	System	19 Aug 2020 18:26:41

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:25:25', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '26c99f1a-42ba-4605-bdca-4249656a2150'	System	19 Aug 2020 18:26:41
User entered 'No (N)'	System	19 Aug 2020 18:26:41

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:25:37', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '26c99f1a-42ba-4605-bdca-4249656a2150' User entered 'No (N)'	System	19 Aug 2020 18:26:41
	System	19 Aug 2020 18:26:41

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:25:50', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '26c99f1a-42ba-4605-bdca-4249656a2150' User entered 'None (1)'	System	19 Aug 2020 18:26:41
	System	19 Aug 2020 18:26:41

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:26:38', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '26c99f1a-42ba-4605-bdca-4249656a2150'	System	19 Aug 2020 18:26:41
User entered '19 Aug 2020 14:26'	System	19 Aug 2020 18:26:41



**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Aug 2020 14:02'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Aug 2020 16:32'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:34:26', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'ed610e47-b75b-4e26-a48e-46dc67fc32b5' User entered 'None (1)'	System	20 Aug 2020 01:35:22
	System	20 Aug 2020 01:35:22

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:34:40', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'ed610e47-b75b-4e26-a48e-46dc67fc32b5' User entered 'No (N)'	System	20 Aug 2020 01:35:22
	System	20 Aug 2020 01:35:22

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:34:53', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'ed610e47-b75b-4e26-a48e-46dc67fc32b5' User entered 'No (N)'	System	20 Aug 2020 01:35:22
	System	20 Aug 2020 01:35:22

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:35:12', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'ed610e47-b75b-4e26-a48e-46dc67fc32b5' User entered 'None (1)'	System	20 Aug 2020 01:35:22
	System	20 Aug 2020 01:35:22

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:35:20', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'ed610e47-b75b-4e26-a48e-46dc67fc32b5' User entered '19 Aug 2020 21:35'	System	20 Aug 2020 01:35:22
	System	20 Aug 2020 01:35:22



**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Aug 2020 17:27'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 2'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:11:20', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'e5034f8a-6228-4e6c-9601-e333bdce677b' User entered 'None (1)'	System	20 Aug 2020 16:11:31
	System	20 Aug 2020 16:11:31

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:10:21', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'e5034f8a-6228-4e6c-9601-e333bdce677b' User entered 'No (N)'	System	20 Aug 2020 16:11:31
	System	20 Aug 2020 16:11:31

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:10:30', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'e5034f8a-6228-4e6c-9601-e333bdce677b' User entered 'No (N)'	System	20 Aug 2020 16:11:31
	System	20 Aug 2020 16:11:31

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:10:43', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'e5034f8a-6228-4e6c-9601-e333bdce677b' User entered 'None (1)'	System	20 Aug 2020 16:11:31
	System	20 Aug 2020 16:11:31

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:11:28', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'e5034f8a-6228-4e6c-9601-e333bdce677b' User entered '20 Aug 2020 12:11'	System	20 Aug 2020 16:11:31
	System	20 Aug 2020 16:11:31



**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 3'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:00:56', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '5c828dff-7acf-499e-a666-174c24c68283'	System	21 Aug 2020 16:01:40
User entered 'None (1)'	System	21 Aug 2020 16:01:40

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:01:07', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '5c828dff-7acf-499e-a666-174c24c68283'	System	21 Aug 2020 16:01:40
User entered 'No (N)'	System	21 Aug 2020 16:01:40

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:01:15', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '5c828dff-7acf-499e-a666-174c24c68283'	System	21 Aug 2020 16:01:40
User entered 'No (N)'	System	21 Aug 2020 16:01:40

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:01:26', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '5c828dff-7acf-499e-a666-174c24c68283'	System	21 Aug 2020 16:01:40
User entered 'None (1)'	System	21 Aug 2020 16:01:40

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:01:36', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '5c828dff-7acf-499e-a666-174c24c68283'	System	21 Aug 2020 16:01:40
User entered '21 Aug 2020 12:01'	System	21 Aug 2020 16:01:40



**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 4'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06



US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 5'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06



US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 6'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06



US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 17:51:36



US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 7'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 17:51:36

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:26:47', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '7ebf2da1-2539-4b78-aefa-7a21c40f054e' User entered 'None (0)'	System	19 Aug 2020 18:27:44
	System	19 Aug 2020 18:27:44

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:26:52', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '7ebf2da1-2539-4b78-aefa-7a21c40f054e' User entered 'None (0)'	System	19 Aug 2020 18:27:44
	System	19 Aug 2020 18:27:44

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:27:02', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '7ebf2da1-2539-4b78-aeфа-7a21c40f054e' User entered 'None (0)'	System	19 Aug 2020 18:27:44
	System	19 Aug 2020 18:27:44

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:27:08', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '7ebf2da1-2539-4b78-ae6a-7a21c40f054e' User entered 'None (0)'	System	19 Aug 2020 18:27:44
	System	19 Aug 2020 18:27:44

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:27:15', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '7ebf2da1-2539-4b78-aefa-7a21c40f054e' User entered 'None (0)'	System	19 Aug 2020 18:27:44
	System	19 Aug 2020 18:27:44



**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:27:22', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '7ebf2da1-2539-4b78-aefa-7a21c40f054e' User entered 'None (0)'	System	19 Aug 2020 18:27:44
	System	19 Aug 2020 18:27:44

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:27:36', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '7ebf2da1-2539-4b78-aefa-7a21c40f054e' User entered 'No (N)'	System	19 Aug 2020 18:27:44
	System	19 Aug 2020 18:27:44

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T14:27:42', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '7ebf2da1-2539-4b78-aefa-7a21c40f054e' User entered '19 Aug 2020 14:27'	System	19 Aug 2020 18:27:44
	System	19 Aug 2020 18:27:44

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Aug 2020 14:02'	System	19 Aug 2020 17:51:36

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Aug 2020 16:32'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 17:51:36

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:32:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:31:04', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '958b26b2-584b-4452-84ca-ae90790c79e7' User entered 'None (0)'	System	20 Aug 2020 01:34:05
	System	20 Aug 2020 01:34:05

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:32:11**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:31:37', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '958b26b2-584b-4452-84ca-ae90790c79e7' User entered 'None (0)'	System	20 Aug 2020 01:34:05
	System	20 Aug 2020 01:34:05



US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:31:53', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '958b26b2-584b-4452-84ca-ae90790c79e7' User entered 'None (0)'	System	20 Aug 2020 01:34:05
	System	20 Aug 2020 01:34:05

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:32:11', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '958b26b2-584b-4452-84ca-ae90790c79e7' User entered 'None (0)'	System	20 Aug 2020 01:34:05
	System	20 Aug 2020 01:34:05

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:32:11**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:32:25', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '958b26b2-584b-4452-84ca-ae90790c79e7' User entered 'None (0)'	System	20 Aug 2020 01:34:05
	System	20 Aug 2020 01:34:05

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:32:38', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '958b26b2-584b-4452-84ca-ae90790c79e7' User entered 'None (0)'	System	20 Aug 2020 01:34:05
	System	20 Aug 2020 01:34:05

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:32:57', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '958b26b2-584b-4452-84ca-ae90790c79e7'	System	20 Aug 2020 01:34:05
User entered 'No (N)'	System	20 Aug 2020 01:34:05

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-19T21:34:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '958b26b2-584b-4452-84ca-ae90790c79e7' User entered '19 Aug 2020 21:34'	System	20 Aug 2020 01:34:05
	System	20 Aug 2020 01:34:05

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Aug 2020 17:27'	System	19 Aug 2020 17:51:36

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 17:51:36



**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 2'	System	19 Aug 2020 17:51:36

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:32:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:11:44', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '206738ea-972e-4a93-b57b-742a24b6543a' User entered 'None (0)'	System	20 Aug 2020 16:13:01
	System	20 Aug 2020 16:13:01

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:32:11**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:11:53', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '206738ea-972e-4a93-b57b-742a24b6543a' User entered 'None (0)'	System	20 Aug 2020 16:13:01
	System	20 Aug 2020 16:13:01

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:12:05', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '206738ea-972e-4a93-b57b-742a24b6543a' User entered 'None (0)'	System	20 Aug 2020 16:13:01
	System	20 Aug 2020 16:13:01

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:12:17', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '206738ea-972e-4a93-b57b-742a24b6543a' User entered 'None (0)'	System	20 Aug 2020 16:13:01
	System	20 Aug 2020 16:13:01

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:32:11**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:12:28', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '206738ea-972e-4a93-b57b-742a24b6543a' User entered 'None (0)'	System	20 Aug 2020 16:13:01
	System	20 Aug 2020 16:13:01

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:12:37', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '206738ea-972e-4a93-b57b-742a24b6543a' User entered 'None (0)'	System	20 Aug 2020 16:13:01
	System	20 Aug 2020 16:13:01

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:12:50', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '206738ea-972e-4a93-b57b-742a24b6543a' User entered 'No (N)'	System	20 Aug 2020 16:13:01
	System	20 Aug 2020 16:13:01



**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-20T12:12:56', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '206738ea-972e-4a93-b57b-742a24b6543a' User entered '20 Aug 2020 12:12'	System	20 Aug 2020 16:13:01
	System	20 Aug 2020 16:13:01

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 3'	System	19 Aug 2020 17:51:36

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:32:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:02:17', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57451cc8-7e50-4230-8998-7d9561a39b93'	System	21 Aug 2020 16:03:05
User entered 'None (0)'	System	21 Aug 2020 16:03:05

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:02:22', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57451cc8-7e50-4230-8998-7d9561a39b93'	System	21 Aug 2020 16:03:05
User entered 'None (0)'	System	21 Aug 2020 16:03:05

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:02:28', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57451cc8-7e50-4230-8998-7d9561a39b93'	System	21 Aug 2020 16:03:05
User entered 'None (0)'	System	21 Aug 2020 16:03:05

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:02:35', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57451cc8-7e50-4230-8998-7d9561a39b93'	System	21 Aug 2020 16:03:05
User entered 'None (0)'	System	21 Aug 2020 16:03:05



US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:02:40', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57451cc8-7e50-4230-8998-7d9561a39b93'	System	21 Aug 2020 16:03:05
User entered 'None (0)'	System	21 Aug 2020 16:03:05

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:32:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:02:48', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57451cc8-7e50-4230-8998-7d9561a39b93'	System	21 Aug 2020 16:03:05
User entered 'None (0)'	System	21 Aug 2020 16:03:05

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:02:54', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57451cc8-7e50-4230-8998-7d9561a39b93'	System	21 Aug 2020 16:03:05
User entered 'No (N)'	System	21 Aug 2020 16:03:05

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-08-21T12:03:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57451cc8-7e50-4230-8998-7d9561a39b93'	System	21 Aug 2020 16:03:05
User entered '21 Aug 2020 12:03'	System	21 Aug 2020 16:03:05

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 4'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:32:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 17:51:36



US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 5'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 6'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 7'	System	19 Aug 2020 17:51:36



US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:32:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 17:51:36

**US3172211**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 17:51:36

US3172211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 16:37:28

US3172211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '27 Aug 2020'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 16:37:28

**US3172211**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 16:37:28

US3172211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 16:37:28

US3172211

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 16:37:35

**US3172211**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'I'	System	31 Aug 2020 16:37:35



US3172211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 17:10:01

US3172211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '02 Sep 2020'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 17:10:01

**US3172211**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 17:10:01

US3172211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 17:10:01

US3172211

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 17:10:06

**US3172211**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'I'	System	03 Sep 2020 17:10:06

**US3172211**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Sep 2020 18:40:56

**US3172211**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '09 Sep 2020'	Jessie Downs (b) (4) (b) (4)	10 Sep 2020 18:40:56



US3172211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	10 Sep 2020 18:40:56

US3172211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	10 Sep 2020 18:40:56

US3172211

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Sep 2020 18:41:04

**US3172211**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'I'	System	10 Sep 2020 18:41:04

US3172211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User closed query 'Per GCL Lab Recon: GCL is reporting receiving a SARS sample dated 28Sep2020, however, no COVID-19 Assessment Contact, Symptom Log, Diagnostic test, or Illness visit has been completed matching this date. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 04:16:24
Query 'Per GCL Lab Recon: GCL is reporting receiving a SARS sample dated 28Sep2020, however, no COVID-19 Assessment Contact, Symptom Log, Diagnostic test, or Illness visit has been completed matching this date. Please reconcile.' answered with 'Data was entered.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:32
User opened query 'Per GCL Lab Recon: GCL is reporting receiving a SARS sample dated 28Sep2020, however, no COVID-19 Assessment Contact, Symptom Log, Diagnostic test, or Illness visit has been completed matching this date. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 21:58:03
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 15:40:32

US3172211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 15:40:32

**US3172211**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 15:40:32

**US3172211**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'VISIT2'	System	16 Sep 2020 15:40:32



US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

**US3172211**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '09:45'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

**US3172211**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered '16 Sep 2020 09:45'	System	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '36.9' C	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

**US3172211**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31



US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '96'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'bpm'	System	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '17'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'breaths/min'	System	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '117'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'mmHg'	System	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '77'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'mmHg'	System	24 Sep 2020 15:42:31



US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '12:01'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

**US3172211**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered '16 Sep 2020 12:01'	System	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '37.1' C	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31



US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '89'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'bpm'	System	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '16'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'breaths/min'	System	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '139'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'mmHg'	System	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '85'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:42:31

US3172211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'mmHg'	System	24 Sep 2020 15:42:31



US3172211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:38:29

**US3172211**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:32:11**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:38:29

US3172211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 15:39:59

US3172211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 15:39:59

US3172211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

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)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	16 Sep 2020 15:39:59
	(b) (4)	

US3172211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 15:39:59

US3172211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 15:39:59

US3172211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '11:31'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 15:39:59



**US3172211**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:32:11**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered '16 Sep 2020 11:31'	System	16 Sep 2020 15:39:59

US3172211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 15:39:59

US3172211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'ONCE'	System	16 Sep 2020 15:39:59

US3172211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 15:39:59

US3172211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:37:53

US3172211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:37:53

US3172211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '11:14'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:37:53

**US3172211**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:32:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered '16 Sep 2020 11:14'	System	24 Sep 2020 15:37:53



US3172211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:32:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:38:14

**US3172211**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:38:14

US3172211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:38:14

US3172211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '11:04'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:38:14

**US3172211**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered '16 Sep 2020 11:04'	System	24 Sep 2020 15:38:14

**US3172211**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:38:14

US3172211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:38:14

US3172211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '11:04'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:38:14



**US3172211**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered '16 Sep 2020 11:04'	System	24 Sep 2020 15:38:14

US3172211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 15:38:19

**US3172211**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'I'	System	24 Sep 2020 15:38:19

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:15:13', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '5d829bcd-f859-4baa-893c-ad891b0c83de' User entered 'Yes (Y)'	System	16 Sep 2020 16:15:32
	System	16 Sep 2020 16:15:32

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:15:19', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '5d829bcd-f859-4baa-893c-ad891b0c83de' User entered '98.4'	System	16 Sep 2020 16:15:32
	System	16 Sep 2020 16:15:32

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:15:24', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '5d829bcd-f859-4baa-893c-ad891b0c83de' User entered 'No (N)'	System	16 Sep 2020 16:15:32
	System	16 Sep 2020 16:15:32

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:15:27', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '5d829bcd-f859-4baa-893c-ad891b0c83de' User entered '16 Sep 2020 12:15'	System	16 Sep 2020 16:15:32
	System	16 Sep 2020 16:15:32



US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '16 Sep 2020 11:51'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '16 Sep 2020 14:21'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '16 Sep 2020 15:16'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 2'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 3'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 4'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 5'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 6'	System	16 Sep 2020 15:39:59



US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:39:59



US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 7'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:39:59



US3172211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:14:44', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57254094-fe23-44f9-a1a9-2aadd9445883'	System	16 Sep 2020 16:15:09
User entered 'None (1)'	System	16 Sep 2020 16:15:09

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:14:51', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57254094-fe23-44f9-a1a9-2aadd9445883' User entered 'No (N)'	System	16 Sep 2020 16:15:09
	System	16 Sep 2020 16:15:09

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:14:57', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57254094-fe23-44f9-a1a9-2aadd9445883' User entered 'No (N)'	System	16 Sep 2020 16:15:09
	System	16 Sep 2020 16:15:09

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:15:05', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57254094-fe23-44f9-a1a9-2aadd9445883' User entered 'None (1)'	System	16 Sep 2020 16:15:09
	System	16 Sep 2020 16:15:09

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:15:07', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '57254094-fe23-44f9-a1a9-2aadd9445883' User entered '16 Sep 2020 12:15'	System	16 Sep 2020 16:15:09
	System	16 Sep 2020 16:15:09

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '16 Sep 2020 11:51'	System	16 Sep 2020 15:39:59



**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '16 Sep 2020 14:21'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '16 Sep 2020 15:16'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 2'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 3'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 4'	System	16 Sep 2020 15:39:59



US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:39:59



US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 5'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 6'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 7'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:32:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 15:39:59



US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:14:06', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '67171eb2-8e65-436f-ab4f-1661ef873cb0' User entered 'None (0)'	System	16 Sep 2020 16:14:39
	System	16 Sep 2020 16:14:39

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:14:09', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '67171eb2-8e65-436f-ab4f-1661ef873cb0' User entered 'None (0)'	System	16 Sep 2020 16:14:39
	System	16 Sep 2020 16:14:39

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:14:13', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '67171eb2-8e65-436f-ab4f-1661ef873cb0' User entered 'None (0)'	System	16 Sep 2020 16:14:39
	System	16 Sep 2020 16:14:39

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:14:19', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '67171eb2-8e65-436f-ab4f-1661ef873cb0' User entered 'None (0)'	System	16 Sep 2020 16:14:39
	System	16 Sep 2020 16:14:39

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:14:22', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '67171eb2-8e65-436f-ab4f-1661ef873cb0' User entered 'None (0)'	System	16 Sep 2020 16:14:39
	System	16 Sep 2020 16:14:39

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:14:25', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '67171eb2-8e65-436f-ab4f-1661ef873cb0' User entered 'None (0)'	System	16 Sep 2020 16:14:39
	System	16 Sep 2020 16:14:39

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:14:34', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '67171eb2-8e65-436f-ab4f-1661ef873cb0' User entered 'No (N)'	System	16 Sep 2020 16:14:39
	System	16 Sep 2020 16:14:39

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-09-16T12:14:37', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '67171eb2-8e65-436f-ab4f-1661ef873cb0' User entered '16 Sep 2020 12:14'	System	16 Sep 2020 16:14:39
	System	16 Sep 2020 16:14:39



**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '16 Sep 2020 11:51'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '16 Sep 2020 14:21'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:32:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '16 Sep 2020 15:16'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 2'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 15:39:59



US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 3'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 4'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:32:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 5'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:32:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 15:39:59



**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 6'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	16 Sep 2020 15:39:59
User entered 'Day 7'	System	16 Sep 2020 15:39:59

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:32:11**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06



US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

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 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06

US3172211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:32:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 15:39:59

**US3172211**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:32:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 15:39:59

US3172211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 13:27:22



US3172211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '23 Sep 2020'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 13:27:22

US3172211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 13:27:22

US3172211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 13:27:22

US3172211

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 13:27:26

**US3172211**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'I'	System	02 Oct 2020 13:27:26

**US3172211**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 13:27:45

**US3172211**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '30 Sep 2020'	Jessie Downs (b) (4)	02 Oct 2020 13:27:45
	(b) (4)	

**US3172211**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	02 Oct 2020 13:27:45
	(b) (4)	



US3172211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 13:27:45

US3172211

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 19:37:47
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 19:53:10
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 13:27:49

**US3172211**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered '1'	System	12 Nov 2020 19:37:47
User entered empty.	System	07 Oct 2020 19:53:10
User entered '1'	System	02 Oct 2020 13:27:49

**US3172211**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 19:38:08

**US3172211**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '07 Oct 2020'	Jessie Downs (b) (4)	12 Nov 2020 19:38:08
	(b) (4)	

US3172211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 19:38:08

US3172211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 19:38:08

US3172211

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 19:38:15



**US3172211**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'I'	System	12 Nov 2020 19:38:15

US3172211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:01:53

US3172211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 11:08:17
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Date correct as entered.' (Site from System).	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:16:06
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	12 Nov 2020 20:01:53
User entered '26 Oct 2020'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:01:53

US3172211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:01:53

**US3172211**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'VISIT3'	System	12 Nov 2020 20:01:53

US3172211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:19:17

US3172211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '26 Oct 2020'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:19:17

US3172211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '13:25'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:19:17



**US3172211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered '26 Oct 2020 13:25'	System	12 Nov 2020 20:19:17

US3172211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '37.0' C	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:19:17

US3172211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:19:17

US3172211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:19:17

**US3172211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '90'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:19:17

**US3172211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'bpm'	System	12 Nov 2020 20:19:17

US3172211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '17'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:19:17

US3172211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'breaths/min'	System	12 Nov 2020 20:19:17



US3172211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '132'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:19:17

**US3172211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'mmHg'	System	12 Nov 2020 20:19:17

US3172211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '82'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:19:17

**US3172211**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'mmHg'	System	12 Nov 2020 20:19:17

US3172211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12

US3172211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12

US3172211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:16:23

US3172211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:16:23



US3172211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:17:07

US3172211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '26 Oct 2020'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:17:07

**US3172211**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:32:11**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '15:08'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:17:07

**US3172211**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:32:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered '26 Oct 2020 15:08'	System	12 Nov 2020 20:17:07

US3172211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:17:12

**US3172211**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'I'	System	12 Nov 2020 20:17:12

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 64'	System	19 Aug 2020 17:51:36

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27
Data entry locked.	System	19 Aug 2020 17:51:36
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 17:51:36

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:02:27
Data entry locked.	System	19 Aug 2020 17:51:36
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 17:51:36

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 71'	System	19 Aug 2020 17:51:36

US3172211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-10-26T13:49:29', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '943c1986-0ee6-4ab5-bdad-babe4bc11008' User entered 'No (N)'	System	26 Oct 2020 17:49:39
	System	26 Oct 2020 17:49:39

US3172211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

Have you been exposed to someone with 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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-10-26T13:49:21', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '943c1986-0ee6-4ab5-bdad-babe4bc11008'	System	26 Oct 2020 17:49:39
User entered 'No (N)'	System	26 Oct 2020 17:49:39

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-10-26T13:49:36', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '943c1986-0ee6-4ab5-bdad-babe4bc11008' User entered '26 Oct 2020 13:49:36'	System	26 Oct 2020 17:49:39
	System	26 Oct 2020 17:49:39

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 17:51:36

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 17:51:36



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 78'	System	19 Aug 2020 17:51:36

US3172211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

[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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-11-02T00:04:28', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '67013b87-abcc-4faf-a3f0-c50dc84a3f52'	System	02 Nov 2020 05:04:55
User entered 'No (N)'	System	02 Nov 2020 05:04:55

US3172211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

Have you been exposed to someone with 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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-11-02T00:04:23', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '67013b87-abcc-4faf-a3f0-c50dc84a3f52'	System	02 Nov 2020 05:04:55
User entered 'No (N)'	System	02 Nov 2020 05:04:55

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-11-02T00:04:53', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '67013b87-abcc-4faf-a3f0-c50dc84a3f52' User entered '02 Nov 2020 00:04:53'	System	02 Nov 2020 05:04:55
	System	02 Nov 2020 05:04:55

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 17:51:36

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 17:51:36

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered 'Day 92'	System	19 Aug 2020 17:51:36

US3172211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

[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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-11-16T00:43:47', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'ba6cb52a-b338-4d6b-8072-8894d56f585a'	System	16 Nov 2020 05:44:49
User entered 'No (N)'	System	16 Nov 2020 05:44:49



US3172211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:11

Have you been exposed to someone with 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 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-11-16T00:44:17', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'ba6cb52a-b338-4d6b-8072-8894d56f585a' User entered 'No (N)'	System	16 Nov 2020 05:44:49
	System	16 Nov 2020 05:44:49

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-11-16T00:44:47', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'ba6cb52a-b338-4d6b-8072-8894d56f585a' User entered '16 Nov 2020 00:44:47'	System	16 Nov 2020 05:44:49
	System	16 Nov 2020 05:44:49

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 17:51:36

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:15:06
Data entry locked.	System	19 Aug 2020 17:51:36
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 17:51:36

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-11-23T00:03:25', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '9b90bf36-8d6d-4d37-952f-739bc607f2fd' User entered 'No (N)'	System	23 Nov 2020 05:03:48

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-11-23T00:03:35', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '9b90bf36-8d6d-4d37-952f-739bc607f2fd' User entered 'No (N)'	System	23 Nov 2020 05:03:48
	System	23 Nov 2020 05:03:48

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-11-23T00:03:44', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '9b90bf36-8d6d-4d37-952f-739bc607f2fd' User entered '23 Nov 2020 00:03:44'	System	23 Nov 2020 05:03:48
	System	23 Nov 2020 05:03:48



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-11-27T00:18:38', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '48b5d14d-9f50-4f12-8dc6-e6991a717a5c' User entered 'No (N)'	System	27 Nov 2020 05:18:50
	System	27 Nov 2020 05:18:50

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-11-27T00:18:41', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '48b5d14d-9f50-4f12-8dc6-e6991a717a5c' User entered 'No (N)'	System	27 Nov 2020 05:18:50

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-11-27T00:18:47', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '48b5d14d-9f50-4f12-8dc6-e6991a717a5c' User entered '27 Nov 2020 00:18:47'	System	27 Nov 2020 05:18:50
	System	27 Nov 2020 05:18:50

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:02:27



**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:02:27

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-12-05T11:45:16', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '6ff7ab8a-5be2-4031-b31b-d049a978a0ac'	System	05 Dec 2020 16:45:26
User entered 'No (N)'	System	05 Dec 2020 16:45:26

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-12-05T11:45:19', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '6ff7ab8a-5be2-4031-b31b-d049a978a0ac'	System	05 Dec 2020 16:45:26
User entered 'No (N)'	System	05 Dec 2020 16:45:26

**US3172211**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-12-05T11:45:23', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '6ff7ab8a-5be2-4031-b31b-d049a978a0ac' User entered '05 Dec 2020 11:45:23'	System	05 Dec 2020 16:45:26
	System	05 Dec 2020 16:45:26

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-12-11T01:03:58', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'd41d6ae3-bae7-4d42-a4ee-3eed830510c1' User entered 'No (N)'	System	11 Dec 2020 06:04:12
	System	11 Dec 2020 06:04:12



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-12-11T01:04:02', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'd41d6ae3-bae7-4d42-a4ee-3eed830510c1' User entered 'No (N)'	System	11 Dec 2020 06:04:12
	System	11 Dec 2020 06:04:12

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-12-11T01:04:07', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'd41d6ae3-bae7-4d42-a4ee-3eed830510c1' User entered '11 Dec 2020 01:04:07'	System	11 Dec 2020 06:04:12
	System	11 Dec 2020 06:04:12

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-12-18T03:06:09', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'b39906aa-39ff-4753-b0f4-ebd1a4988aec'	System	18 Dec 2020 08:06:21
User entered 'No (N)'	System	18 Dec 2020 08:06:21

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-12-18T03:06:13', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'b39906aa-39ff-4753-b0f4-ebd1a4988aec'	System	18 Dec 2020 08:06:21
User entered 'No (N)'	System	18 Dec 2020 08:06:21

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-12-18T03:06:18', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'b39906aa-39ff-4753-b0f4-ebd1a4988aec' User entered '18 Dec 2020 03:06:18'	System	18 Dec 2020 08:06:21
	System	18 Dec 2020 08:06:21



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-12-25T07:59:47', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '53920e08-33d7-453f-aaf7-677e96b8b2ad' User entered 'No (N)'	System	25 Dec 2020 12:59:59
	System	25 Dec 2020 12:59:59

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-12-25T07:59:50', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '53920e08-33d7-453f-aaf7-677e96b8b2ad' User entered 'No (N)'	System	25 Dec 2020 12:59:59
	System	25 Dec 2020 12:59:59

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2020-12-25T07:59:56', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '53920e08-33d7-453f-aaf7-677e96b8b2ad' User entered '25 Dec 2020 07:59:56'	System	25 Dec 2020 12:59:59
	System	25 Dec 2020 12:59:59

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (ae1bbebbd7a716d5)', Time: '2021-01-01T17:49:07', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '023f814a-9bc6-4639-bec0-3e30304e8c02'	System	01 Jan 2021 22:49:19
User entered 'No (N)'	System	01 Jan 2021 22:49:19

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Have you been exposed to someone with 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 (ae1bbebbd7a716d5)', Time: '2021-01-01T17:49:12', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '023f814a-9bc6-4639-bec0-3e30304e8c02'	System	01 Jan 2021 22:49:19
User entered 'No (N)'	System	01 Jan 2021 22:49:19

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ae1bbebbd7a716d5)', Time: '2021-01-01T17:49:16', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '023f814a-9bc6-4639-bec0-3e30304e8c02'	System	01 Jan 2021 22:49:19
User entered '01 Jan 2021 17:49:16'	System	01 Jan 2021 22:49:19

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (ae1bbebbd7a716d5)', Time: '2021-01-08T08:38:56', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c5b8fcc1-f87d-41b4-9076-93408fa3792c'	System	08 Jan 2021 13:39:12
User entered 'No (N)'	System	08 Jan 2021 13:39:12



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Have you been exposed to someone with 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 (ae1bbebbd7a716d5)', Time: '2021-01-08T08:39:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c5b8fcc1-f87d-41b4-9076-93408fa3792c'	System	08 Jan 2021 13:39:12
User entered 'No (N)'	System	08 Jan 2021 13:39:12

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ae1bbebbd7a716d5)', Time: '2021-01-08T08:39:06', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c5b8fcc1-f87d-41b4-9076-93408fa3792c'	System	08 Jan 2021 13:39:12
User entered '08 Jan 2021 08:39:06'	System	08 Jan 2021 13:39:12

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (ae1bbebbd7a716d5)', Time: '2021-01-15T21:37:39', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '6a8142a5-5403-4c99-ab56-88ca0a77b16d'	System	16 Jan 2021 02:37:53
User entered 'No (N)'	System	16 Jan 2021 02:37:53

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Have you been exposed to someone with 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 (ae1bbebbd7a716d5)', Time: '2021-01-15T21:37:43', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '6a8142a5-5403-4c99-ab56-88ca0a77b16d'	System	16 Jan 2021 02:37:53
User entered 'No (N)'	System	16 Jan 2021 02:37:53

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ae1bbebbd7a716d5)', Time: '2021-01-15T21:37:48', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '6a8142a5-5403-4c99-ab56-88ca0a77b16d'	System	16 Jan 2021 02:37:53
User entered '15 Jan 2021 21:37:48'	System	16 Jan 2021 02:37:53



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-01-26T09:08:20', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c5242551-ceb3-443b-b803-e8ca42a81d4c' User entered 'No (N)'	System	26 Jan 2021 14:08:48
	System	26 Jan 2021 14:08:48

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-01-26T09:08:23', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c5242551-ceb3-443b-b803-e8ca42a81d4c' User entered 'No (N)'	System	26 Jan 2021 14:08:48
	System	26 Jan 2021 14:08:48

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-01-26T09:08:26', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c5242551-ceb3-443b-b803-e8ca42a81d4c' User entered '26 Jan 2021 09:08:26'	System	26 Jan 2021 14:08:48
	System	26 Jan 2021 14:08:48

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-01-29T00:01:19', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '44bfaae8-ff6b-4570-88d7-e80ff7faae71'	System	29 Jan 2021 05:01:44
User entered 'No (N)'	System	29 Jan 2021 05:01:44

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-01-29T00:01:23', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '44bfaae8-ff6b-4570-88d7-e80ff7faae71'	System	29 Jan 2021 05:01:44
User entered 'No (N)'	System	29 Jan 2021 05:01:44

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-01-29T00:01:27', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '44bfaae8-ff6b-4570-88d7-e80ff7faae71' User entered '29 Jan 2021 00:01:27'	System	29 Jan 2021 05:01:44

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-02-05T10:54:31', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'b682ec14-6b39-4d36-8b2b-04f39fc434b8' User entered 'No (N)'	System	05 Feb 2021 15:54:40
	System	05 Feb 2021 15:54:40



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-02-05T10:54:34', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'b682ec14-6b39-4d36-8b2b-04f39fc434b8' User entered 'No (N)'	System	05 Feb 2021 15:54:40
	System	05 Feb 2021 15:54:40

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-02-05T10:54:38', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'b682ec14-6b39-4d36-8b2b-04f39fc434b8' User entered '05 Feb 2021 10:54:38'	System	05 Feb 2021 15:54:40
	System	05 Feb 2021 15:54:40

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-02-12T00:06:58', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '33441562-a6b5-4266-a047-b6ac38c4cbfd' User entered 'No (N)'	System	12 Feb 2021 05:07:10
	System	12 Feb 2021 05:07:10

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-02-12T00:07:01', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '33441562-a6b5-4266-a047-b6ac38c4cbfd' User entered 'No (N)'	System	12 Feb 2021 05:07:10
	System	12 Feb 2021 05:07:10

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-02-12T00:07:09', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '33441562-a6b5-4266-a047-b6ac38c4cbfd' User entered '12 Feb 2021 00:07:09'	System	12 Feb 2021 05:07:10
	System	12 Feb 2021 05:07:10



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-02-19T00:01:37', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '056da0b2-961f-4b8a-a1e0-cda8318bb9c0' User entered 'No (N)'	System	19 Feb 2021 05:02:46
	System	19 Feb 2021 05:02:46

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-02-19T00:01:40', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '056da0b2-961f-4b8a-a1e0-cda8318bb9c0' User entered 'No (N)'	System	19 Feb 2021 05:02:46

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-02-19T00:01:44', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '056da0b2-961f-4b8a-a1e0-cda8318bb9c0' User entered '19 Feb 2021 00:01:44'	System	19 Feb 2021 05:02:46
	System	19 Feb 2021 05:02:46

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-02-26T11:08:59-05:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c4bcf14d-6af3-446a-9aeb-31a0b97cf6df' User entered 'No (N)'	System	26 Feb 2021 16:09:14
	System	26 Feb 2021 16:09:14

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-02-26T11:09:02-05:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c4bcf14d-6af3-446a-9aeb-31a0b97cf6df' User entered 'No (N)'	System	26 Feb 2021 16:09:14
	System	26 Feb 2021 16:09:14

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-02-26T11:09:07-05:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c4bcf14d-6af3-446a-9aeb-31a0b97cf6df' User entered '26 Feb 2021 16:09:07'	System	26 Feb 2021 16:09:14
	System	26 Feb 2021 16:09:14

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-03-05T00:30:28-05:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'ad1401da-9b66-4c63-98bb-14ecaadc818e' User entered 'No (N)'	System	05 Mar 2021 05:30:41
	System	05 Mar 2021 05:30:41



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-03-05T00:30:32-05:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'ad1401da-9b66-4c63-98bb-14ecaadc818e'	System	05 Mar 2021 05:30:41
User entered 'No (N)'	System	05 Mar 2021 05:30:41

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-03-05T00:30:36-05:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'ad1401da-9b66-4c63-98bb-14ecaadc818e' User entered '05 Mar 2021 00:30:36'	System	05 Mar 2021 05:30:41
	System	05 Mar 2021 05:30:41

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-03-12T00:02:58-05:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '02504c85-da77-43e9-a90f-8e08e52805f4'	System	12 Mar 2021 05:04:21
User entered 'No (N)'	System	12 Mar 2021 05:04:21

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-03-12T00:03:01-05:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '02504c85-da77-43e9-a90f-8e08e52805f4'	System	12 Mar 2021 05:04:21
User entered 'No (N)'	System	12 Mar 2021 05:04:21

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-03-12T00:03:10-05:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '02504c85-da77-43e9-a90f-8e08e52805f4' User entered '12 Mar 2021 00:03:10'	System	12 Mar 2021 05:04:21
	System	12 Mar 2021 05:04:21



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-03-19T14:39:36-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '83365fea-4e1a-461e-b14b-28cec8ed0185'	System	19 Mar 2021 18:39:47
User entered 'No (N)'	System	19 Mar 2021 18:39:47

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-03-19T14:39:39-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '83365fea-4e1a-461e-b14b-28cec8ed0185'	System	19 Mar 2021 18:39:47
User entered 'No (N)'	System	19 Mar 2021 18:39:47

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-03-19T14:39:42-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '83365fea-4e1a-461e-b14b-28cec8ed0185'	System	19 Mar 2021 18:39:47
User entered '19 Mar 2021 14:39:42'	System	19 Mar 2021 18:39:47

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-03-26T00:48:43-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'bfc572b2-f624-4563-8e63-ecc03a0e65e4'	System	26 Mar 2021 04:48:59
User entered 'No (N)'	System	26 Mar 2021 04:48:59

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-03-26T00:48:46-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'bfc572b2-f624-4563-8e63-ecc03a0e65e4'	System	26 Mar 2021 04:48:59
User entered 'No (N)'	System	26 Mar 2021 04:48:59

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-03-26T00:48:53-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'bfc572b2-f624-4563-8e63-ecc03a0e65e4' User entered '26 Mar 2021 00:48:53'	System	26 Mar 2021 04:48:59
	System	26 Mar 2021 04:48:59

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-04-02T19:26:07-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '0f196ee5-dc72-486c-bad8-e9004e7937ee' User entered 'No (N)'	System	02 Apr 2021 23:26:17
	System	02 Apr 2021 23:26:17



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-04-02T19:26:10-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '0f196ee5-dc72-486c-bad8-e9004e7937ee' User entered 'No (N)'	System	02 Apr 2021 23:26:17
	System	02 Apr 2021 23:26:17

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-04-02T19:26:14-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '0f196ee5-dc72-486c-bad8-e9004e7937ee' User entered '02 Apr 2021 19:26:14'	System	02 Apr 2021 23:26:17
	System	02 Apr 2021 23:26:17

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-04-09T00:30:45-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '0910efc6-6fce-4bef-8dba-0beb49db94e2'	System	09 Apr 2021 04:30:57
User entered 'No (N)'	System	09 Apr 2021 04:30:57

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-04-09T00:30:49-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '0910efc6-6fce-4bef-8dba-0beb49db94e2'	System	09 Apr 2021 04:30:57
User entered 'No (N)'	System	09 Apr 2021 04:30:57

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-04-09T00:30:54-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '0910efc6-6fce-4bef-8dba-0beb49db94e2' User entered '09 Apr 2021 00:30:54'	System	09 Apr 2021 04:30:57
	System	09 Apr 2021 04:30:57



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-04-18T12:07:51-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'f5413d61-0fb6-44a5-81b5-363ab807fbce'	System	18 Apr 2021 16:09:09
User entered 'No (N)'	System	18 Apr 2021 16:09:09

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-04-18T12:07:54-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'f5413d61-0fb6-44a5-81b5-363ab807fbce'	System	18 Apr 2021 16:09:09
User entered 'No (N)'	System	18 Apr 2021 16:09:09

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-04-18T12:07:58-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'f5413d61-0fb6-44a5-81b5-363ab807fbce' User entered '18 Apr 2021 12:07:58'	System	18 Apr 2021 16:09:09
	System	18 Apr 2021 16:09:09

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-04-25T18:09:09-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '8c6efbdf-eee5-4a1d-a39f-c1482dbb2b99'	System	25 Apr 2021 22:09:31
User entered 'No (N)'	System	25 Apr 2021 22:09:31

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-04-25T18:09:11-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '8c6efbdf-eee5-4a1d-a39f-c1482dbb2b99'	System	25 Apr 2021 22:09:31
User entered 'No (N)'	System	25 Apr 2021 22:09:31

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-04-25T18:09:28-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: '8c6efbdf-eee5-4a1d-a39f-c1482dbb2b99'	System	25 Apr 2021 22:09:31
User entered '25 Apr 2021 18:09:28'	System	25 Apr 2021 22:09:31

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-05-02T12:16:46-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'e20e3689-77e7-44e6-ac91-d4e8e347784b' User entered 'No (N)'	System	02 May 2021 16:17:02
	System	02 May 2021 16:17:02



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

Have you been exposed to someone with 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 (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-05-02T12:16:48-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'e20e3689-77e7-44e6-ac91-d4e8e347784b' User entered 'No (N)'	System	02 May 2021 16:17:02
	System	02 May 2021 16:17:02

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-05-02T12:16:56-04:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'e20e3689-77e7-44e6-ac91-d4e8e347784b'	System	02 May 2021 16:17:02
User entered '02 May 2021 12:16:56'	System	02 May 2021 16:17:02

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:02:27



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:02:27



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:02:27



**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:02:27

**US3172211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:32:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:02:27
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:02:27

US3172211

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:32:11**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-03-01T15:34:22-05:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c5fea17c-7f30-4c83-9cc4-a5ae1d78ab66'	System	01 Mar 2021 20:34:30
User entered 'No (N)'	System	01 Mar 2021 20:34:30

**US3172211**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:33:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (37B5C865-A596-444E-A56C-9CADAD157D4C)', Time: '2021-03-01T15:34:26-05:00', User OID: 'PatientReportedOutcome (US3172211)', ODM File OID: 'c5fea17c-7f30-4c83-9cc4-a5ae1d78ab66'	System	01 Mar 2021 20:34:30
User entered '01 Mar 2021 15:34:26'	System	01 Mar 2021 20:34:30

US3172211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:19:40

US3172211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '12 Nov 2020'	Jessie Downs (b) (4)	12 Nov 2020 20:19:40
	(b) (4)	

US3172211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:19:40



US3172211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:19:40

US3172211

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Nov 2020 20:19:45

**US3172211**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:12
User entered 'I'	System	12 Nov 2020 20:19:45

**US3172211**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 16:53:16

US3172211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '18 Dec 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 21:02:36
User entered '15 Dec 2020'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 16:53:16

**US3172211**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 16:53:16

US3172211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 16:53:16

US3172211

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Dec 2020 16:53:21



**US3172211**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User entered 'I'	System	17 Dec 2020 16:53:21

**US3172211**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:21:20

US3172211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 05:17:15
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Date confirmed as entered. ' (Site from System).	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:21:35
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	18 Jan 2021 22:21:20
User entered '18 Jan 2021'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:21:20

**US3172211**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:21:20

US3172211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:21:20

US3172211

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:21:08

**US3172211**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User entered 'I'	System	18 Jan 2021 22:21:08

US3172211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	01 Mar 2021 20:36:19



US3172211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	01 Mar 2021 20:36:19

**US3172211**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	01 Mar 2021 20:36:19

US3172211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'missed, subject on open label.'	Mariete Rendon (b) (4) (b) (4)	01 Mar 2021 20:36:19

US3172211

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	01 Mar 2021 20:36:25

**US3172211**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:06
User entered 'I'	System	01 Mar 2021 20:36:25

US3172211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:17:23

US3172211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 10:09:10
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Date confirmed as entered.' (Site from System).	Jessie Downs (b) (4)	12 Apr 2021 19:17:45
	(b) (4)	
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	12 Apr 2021 19:17:23
User entered '12 Apr 2021'	Jessie Downs (b) (4)	12 Apr 2021 19:17:23
	(b) (4)	

US3172211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:17:23



**US3172211**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	12 Apr 2021 19:17:23

US3172211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:18:15

US3172211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '12 Apr 2021'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:18:15

US3172211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '12:06'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:18:15

**US3172211**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 12:06'	System	12 Apr 2021 19:18:15

US3172211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '37.2' C	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:18:15

US3172211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:18:15

US3172211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:18:15



US3172211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '95'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:18:15

**US3172211**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 19:18:15

US3172211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '17'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:18:15

US3172211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 19:18:15

US3172211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '144'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:18:15

**US3172211**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 19:18:15

US3172211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '92'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:18:15

US3172211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 19:18:15



US3172211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:18:32

US3172211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '12 Apr 2021'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:18:32

US3172211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:19:35

US3172211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '12 Apr 2021'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:19:35

US3172211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '13:22'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:19:35

**US3172211**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:32:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 13:22'	System	12 Apr 2021 19:19:35

US3172211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:19:39

**US3172211**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:19:39



US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:11

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '28 Sep 2020'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:24:19

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:11

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '11:54'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:24:19

**US3172211**

**Folder: Covid-19 Assessment 28 Sep 2020**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:32:11**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User entered '28 Sep 2020 11:54'	System	28 Oct 2020 21:24:19

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:11

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:24:19

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:11

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:24:19

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Day 1 (Day 1)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '25 Sep 2020'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16



US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User closed query 'Per CDM: Please clarify what has been updated as it appears that O2 Saturation and or Temperature has not been recorded throughout this Symptom Log. Please go thru each log line and it not collected, please consider recording as "Not Done".' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 04:31:27
Query 'Per CDM: Please clarify what has been updated as it appears that O2 Saturation and or Temperature has not been recorded throughout this Symptom Log. Please go thru each log line and it not collected, please consider recording as "Not Done".' answered with 'data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 17:47:56
User opened query 'Per CDM: Please clarify what has been updated as it appears that O2 Saturation and or Temperature has not been recorded throughout this Symptom Log. Please go thru each log line and it not collected, please consider recording as "Not Done".' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 14:20:45
User closed query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-5 and Temperature for Days 1, 2, 3 and 5. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 14:20:45
Query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-5 and Temperature for Days 1, 2, 3 and 5. If not collected, please consider recording these as NOT DONE' answered with 'Data updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 16:24:41
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	07 Jan 2021 16:24:19
User opened query 'Per CDM: It appears that O2 Saturation is not recorded for Days 1-5 and Temperature for Days 1, 2, 3 and 5. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 11:09:56
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User entered '%'	System	07 Jan 2021 16:24:19
User entered empty.	System	03 Nov 2020 19:30:16

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 17:47:42
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16



US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16



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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:32:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:16

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Day 2 (Day 2)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '26 Sep 2020'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 17:47:42
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User entered '%'	System	11 Jan 2021 17:47:42
User entered empty.	System	03 Nov 2020 19:30:27



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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 17:47:42
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27



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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:32:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (2)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27



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Form: Symptom Log (2)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:27

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Day 3 (Day 3)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '27 Sep 2020'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 17:47:42
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User entered '%'	System	11 Jan 2021 17:47:42
User entered empty.	System	03 Nov 2020 19:30:37

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 17:47:42
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37



US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37



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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:32:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:37

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Day 4 (Day 4)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47



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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '28 Sep 2020'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 17:47:42
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User entered '%'	System	11 Jan 2021 17:47:42
User entered empty.	System	03 Nov 2020 19:30:47

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '37.1' C reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47



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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47



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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:32:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:30:47

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Day 5 (Day 5)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '29 Sep 2020'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26



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Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 17:47:42
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User entered '%'	System	11 Jan 2021 17:47:42
User entered empty.	System	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 17:47:42
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26



US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Mild (Mild)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26



US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:32:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (None)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:38:26

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:11

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '28 Sep 2020'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:24:44

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:11

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:24:44

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:11

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:24:44

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:11

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '28 Sep 2020'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:24:44

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:11

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:24:44



US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:11

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:24:44

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:11

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:24:44

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:11

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:24:44

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:11

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:24:44

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:32:11

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User entered '0'	System	28 Oct 2020 21:24:44

US3172211

Folder: Covid-19 Assessment 28 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:32:11

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:06:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:24:24

**US3172211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

**US3172211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16



US3172211

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:32:11

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mark Kutner (b) (4) (b) (4)	22 Feb 2021 14:10:35 17 Feb 2021 13:08:30
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' answered with 'Tracking #: 914897890473. Accession #: 1F655254246' (Site from DM).	Jessie Downs (b) (4) (b) (4)	23 Jan 2021 14:05:02
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the tracking details in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 10:42:44
User closed query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 28SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 10:42:44
Query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 28SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'day 3 - accession number: 1F655254246. illness day 1 for subject 2211 was collected 28sep20.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 18:17:18
User entered '30 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 18:16:28
User opened query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 28SEP2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 04:13:51
User entered '28 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	29 Dec 2020 14:17:01

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3172211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

**US3172211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

US3172211

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:32:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Jessie Downs (b) (4)	11 Jan 2021 18:16:28
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Dec 2020 14:17:01
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Jessie Downs (b) (4)	28 Oct 2020 21:28:16
	(b) (4)	

US3172211

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:32:11

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	11 Jan 2021 18:16:28
	(b) (4)	
User entered '30 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Dec 2020 14:17:01
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	28 Oct 2020 21:28:16
	(b) (4)	

**US3172211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

US3172211

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:32:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'NA (COVID-19 Negative) (NA)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

**US3172211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16



US3172211

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:32:11

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

US3172211

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:32:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'NA (COVID-19 Negative) (NA)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

**US3172211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

**US3172211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

US3172211

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:32:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'NA (COVID-19 Negative) (NA)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

US3172211

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:32:11

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

**US3172211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

US3172211

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:32:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'NA (COVID-19 Negative) (NA)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16



**US3172211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

**US3172211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:32:11**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

US3172211

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:32:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'NA (COVID-19 Negative) (NA)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

**US3172211**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 09 Jun 2021 15:32:11**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:28:16

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:25:06

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '28 Sep 2020'	Jessie Downs (b) (4)	28 Oct 2020 21:25:06
	(b) (4)	

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4)	28 Oct 2020 21:25:06
	(b) (4)	

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User entered 'SICKD1'	System	28 Oct 2020 21:25:06



US3172211

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:27:09

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '28 Sep 2020'	Jessie Downs (b) (4)	28 Oct 2020 21:27:09
	(b) (4)	

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '11:59'	Jessie Downs (b) (4)	28 Oct 2020 21:27:09
	(b) (4)	

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User entered '28 Sep 2020 11:59'	System	28 Oct 2020 21:27:09

US3172211

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '164.9' cm	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:27:09
DataPoint set to visible.	System	28 Oct 2020 21:25:06

US3172211

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '092.9' kg	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:27:09
DataPoint set to visible.	System	28 Oct 2020 21:25:06

US3172211

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '37.1' C	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:27:09

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:27:09



**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:27:09

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '98'	Jessie Downs (b) (4)	28 Oct 2020 21:27:09
	(b) (4)	

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User entered 'bpm'	System	28 Oct 2020 21:27:09

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '18'	Jessie Downs (b) (4)	28 Oct 2020 21:27:09
	(b) (4)	

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User entered 'breaths/min'	System	28 Oct 2020 21:27:09

US3172211

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:09:09
	(b) (4)	
User entered '165'	Jessie Downs (b) (4)	28 Oct 2020 21:27:09
	(b) (4)	

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User entered 'mmHg'	System	28 Oct 2020 21:27:09

US3172211

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:09:09
User entered '89'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:27:09



US3172211

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User entered 'mmHg'	System	28 Oct 2020 21:27:09

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00

US3172211

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:27:28

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:32:11**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '28 Sep 2020'	Jessie Downs (b) (4)	28 Oct 2020 21:27:28
	(b) (4)	

US3172211

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:32:11

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Oct 2020 21:27:41

**US3172211**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 15:32:11**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:33:00
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '28 Sep 2020'	Jessie Downs (b) (4)	28 Oct 2020 21:27:41
	(b) (4)	

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:47



US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:47

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:47

**US3172211**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	02 Mar 2021 19:52:47

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:52

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:52

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:52

**US3172211**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 19:52:52

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:52



US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:52

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:52

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:52

**US3172211**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 19:52:52

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:52

**US3172211**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 19:52:52

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:52

**US3172211**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 19:52:52



US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:52

**US3172211**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 19:52:52

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:55

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:55

US3172211

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 09 Jun 2021 15:32:11**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:59

US3172211

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:32:11

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Mar 2021 19:52:59

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	25 Feb 2021 16:55:37
	(b) (4)	

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '22 Feb 2021'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:55:37



US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4)	25 Feb 2021 16:55:37
	(b) (4)	

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'UNBLND_DECIDE'	System	25 Feb 2021 16:55:37

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:32:11**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered '06 Jan 2021'	Jessie Downs (b) (4)	25 Feb 2021 16:57:32
	(b) (4)	

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:32:11**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:51
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:05:16

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:32:11**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	25 Feb 2021 16:57:32
	(b) (4)	

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:32:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 17:35:22
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:35:22
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:51
User entered empty. WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:05:16

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:32:11

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User closed query 'Per IRT, subject was unblinded on 09FEB2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:55:48
Query 'Per IRT, subject was unblinded on 09FEB2021. Please review and reconcile.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	08 Apr 2021 19:42:43
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	08 Apr 2021 19:42:14
User entered '09 Feb 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	08 Apr 2021 19:42:14
User opened query 'Per IRT, subject was unblinded on 09FEB2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:08:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '22 Feb 2021'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:57:32

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:32:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:57:32



**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:32:11**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:57:32

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:32:11**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:57:32

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:32:11**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:57:32

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:32:11**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '1'	System	25 Feb 2021 16:57:32

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'I'	System	25 Feb 2021 16:57:32

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	25 Feb 2021 16:59:55
DataPoint set to visible.	System	25 Feb 2021 16:57:32



US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	25 Feb 2021 16:59:55
DataPoint set to visible.	System	25 Feb 2021 16:57:32

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '22 Feb 2021'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered '14:40'	Jessie Downs (b) (4)	25 Feb 2021 16:59:55
	(b) (4)	

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '22 Feb 2021 14:40'	System	25 Feb 2021 16:59:55



US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '36.9' C	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '83'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'bpm'	System	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '19'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'breaths/min'	System	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '135'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55



**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'mmHg'	System	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '77'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'mmHg'	System	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered empty.	System	25 Feb 2021 16:59:55
DataPoint set to visible.	System	25 Feb 2021 16:57:32

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 17:00:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 17:00:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 17:00:14
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 16:59:55
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55



US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '22 Feb 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 17:00:14
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:32:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered '16:19'	Jessie Downs (b) (4)	25 Feb 2021 16:59:55
	(b) (4)	

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '22 Feb 2021 16:19'	System	25 Feb 2021 17:00:14
User entered empty.	System	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '37.0' C	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:32:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '83'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'bpm'	System	25 Feb 2021 16:59:55



US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '17'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'breaths/min'	System	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '130'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'mmHg'	System	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '80'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'mmHg'	System	25 Feb 2021 16:59:55

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:58:22

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered '22 Feb 2021'	Jessie Downs (b) (4)	25 Feb 2021 16:58:22
	(b) (4)	



US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:58:13

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	25 Feb 2021 16:58:13
	(b) (4)	

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	25 Feb 2021 16:58:13
	(b) (4)	

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:32:11**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'mRNA-1273'	System	25 Feb 2021 16:58:13
DataPoint set to visible.	System	25 Feb 2021 16:57:32

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered '22 Feb 2021'	Jessie Downs (b) (4)	25 Feb 2021 16:58:13
	(b) (4)	

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '15:49'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:58:13

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:32:11**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '22 Feb 2021 15:49'	System	25 Feb 2021 16:58:13

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4)	25 Feb 2021 16:58:13
	(b) (4)	



**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:32:11**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'ONCE'	System	25 Feb 2021 16:58:13

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:32:11**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 16:58:13

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:56:03

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '22 Feb 2021'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:56:03

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:32:11**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '15:18'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:56:03

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:32:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '22 Feb 2021 15:18'	System	25 Feb 2021 16:56:03

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:32:11**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:57:03

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:32:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '22 Feb 2021'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:57:03



**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:32:11**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered '15:19'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:57:03

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:32:11**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered '22 Feb 2021 15:19'	System	25 Feb 2021 16:57:03

US3172211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:54:32
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 16:57:55

**US3172211**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:42
User entered 'I'	System	25 Feb 2021 16:57:55

**US3172211**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:32
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	02 Mar 2021 21:37:31
	(b) (4)	

US3172211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:32
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered '02 Mar 2021'	Jessie Downs (b) (4)	02 Mar 2021 21:37:31
	(b) (4)	

US3172211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:32
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	02 Mar 2021 21:37:31
	(b) (4)	

**US3172211**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:32
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	02 Mar 2021 21:37:31
	(b) (4)	



US3172211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:32
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:54:32
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	02 Mar 2021 21:37:35
	(b) (4)	

**US3172211**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:32
User entered '1'	System	02 Mar 2021 21:37:35

**US3172211**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:32
User entered 'I'	System	02 Mar 2021 21:37:35
DataPoint set to visible.	System	02 Mar 2021 21:37:35

**US3172211**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:34:41

**US3172211**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '22 Mar 2021'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:34:41

**US3172211**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[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 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:34:41

**US3172211**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered 'OLD29'	System	23 Mar 2021 16:34:41

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47



US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

**US3172211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '22 Mar 2021'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

**US3172211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '11:37'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

**US3172211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered '22 Mar 2021 11:37'	System	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '36.9' C	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

**US3172211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

**US3172211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '84'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47



**US3172211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered 'bpm'	System	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '13'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered 'breaths/min'	System	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '134'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

**US3172211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered 'mmHg'	System	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '78'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

**US3172211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered 'mmHg'	System	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47



US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '22 Mar 2021'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

**US3172211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '14:25'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

**US3172211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered '22 Mar 2021 14:25'	System	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '36.7' C	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

**US3172211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '76'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47



**US3172211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered 'bpm'	System	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '16'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered 'breaths/min'	System	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '134'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

**US3172211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered 'mmHg'	System	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '89'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:36:47

**US3172211**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered 'mmHg'	System	23 Mar 2021 16:36:47

US3172211

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:35:11



**US3172211**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:32:11**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User entered '22 Mar 2021'	Jessie Downs (b) (4)	23 Mar 2021 16:35:11
	(b) (4)	

US3172211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:35:32

US3172211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:35:32

US3172211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

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 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:35:32

**US3172211**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:32:11**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered 'mRNA-1273'	System	23 Mar 2021 16:35:32
DataPoint set to visible.	System	02 Mar 2021 21:37:35

US3172211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User entered '22 Mar 2021'	Jessie Downs (b) (4)	23 Mar 2021 16:35:32
	(b) (4)	

US3172211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '13:55'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:35:32

**US3172211**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:32:11**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered '22 Mar 2021 13:55'	System	23 Mar 2021 16:35:32



US3172211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:35:32

US3172211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered 'ONCE'	System	23 Mar 2021 16:35:32

US3172211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered 'INTRAMUSCULAR'	System	23 Mar 2021 16:35:32

US3172211

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 16:35:36

**US3172211**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:10
User entered 'I'	System	23 Mar 2021 16:35:36

**US3172211**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:32:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 13:01:49

US3172211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '29 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 13:01:49

US3172211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 13:01:49



US3172211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 13:01:49

US3172211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 13:01:58

**US3172211**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:32:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 13:01:58

US3172211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:20:05

US3172211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 10:09:18
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'Date confirmed as entered.' (Site from System).	Jessie Downs (b) (4)	12 Apr 2021 19:20:18
	(b) (4)	
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	12 Apr 2021 19:20:05
User entered '12 Apr 2021'	Jessie Downs (b) (4)	12 Apr 2021 19:20:05
	(b) (4)	

US3172211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:20:05

**US3172211**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:32:11**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	12 Apr 2021 19:20:05

US3172211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:20:56



US3172211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '12 Apr 2021'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:20:56

US3172211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '12:06'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:20:56

**US3172211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 12:06'	System	12 Apr 2021 19:20:56

US3172211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '37.2' C	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:20:56

US3172211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:20:56

US3172211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:20:56

US3172211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '95'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:20:56

**US3172211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 19:20:56



US3172211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '17'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:20:56

**US3172211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 19:20:56

US3172211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '144'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:20:56

**US3172211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 19:20:56

US3172211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '92'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:20:56

**US3172211**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:32:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 19:20:56

US3172211

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:21:10

US3172211

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '12 Apr 2021'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:21:10



US3172211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:21:27

US3172211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '12 Apr 2021'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:21:27

**US3172211**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:32:11**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '13:22'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:21:27

**US3172211**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:32:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 13:22'	System	12 Apr 2021 19:21:27

US3172211

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:32:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:45:25
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	10 Sep 2020 18:40:29

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 09:34:20
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 09:34:20
	(b) (4)	
Data point term sent to Coder	System	29 Sep 2020 21:48:34
User entered 'rib cage arthralgia (Left sided)'	Mariete Rendon (b) (4)	29 Sep 2020 21:48:01
	(b) (4)	

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01



US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '25 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:32:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 17:57:09
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4)	25 Nov 2020 15:22:32
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	25 Nov 2020 15:22:15
	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:39:38
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	29 Sep 2020 21:48:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '10 Oct 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	25 Nov 2020 15:22:15
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	29 Sep 2020 21:48:01
	(b) (4)	

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:32:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Sep 2020 21:48:01



US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01



US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Related (RELATED)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Related (RELATED)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

None

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01



US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '1'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	25 Nov 2020 15:22:15
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:01:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 16:01:16
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	30 Sep 2020 16:01:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Sep 2020 21:48:01
User entered empty.	Mariete Rendon (b) (4)	29 Sep 2020 21:48:01
	(b) (4)	

US3172211

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:32:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:48:01

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Sep 2020 21:48:01

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 21:48:01

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User closed query 'Per MM: Please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 05:11:57
Query 'Per MM: Please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' answered with 'Yes, COVID test was negative.' (Site from DM).	Mariete Rendon (b) (4)	14 Oct 2020 18:03:57
	(b) (4)	
User opened query 'Per MM: Please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 13:54:36
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Influenza viral infections, PT: Influenza, LLT: Influenza B virus infection - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:16:55
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 16:16:55
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:16:08
User entered 'Influenza B'	Mariete Rendon (b) (4)	30 Sep 2020 16:16:03
	(b) (4)	



**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 21:09:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 21:09:50
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	30 Sep 2020 21:09:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 16:16:03
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:16:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '25 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:32:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:16:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 15:37:05
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	30 Sep 2020 16:16:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	14 Oct 2020 18:05:13
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	14 Oct 2020 18:05:13
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	14 Oct 2020 15:37:05
User entered '5 Oct 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 15:37:05
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:16:03
	(b) (4)	



**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:32:11**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:32:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03



US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

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Generated On: 09 Jun 2021 15:32:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03



**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (NONE)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

None

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '1'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:05:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:32:11**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:16:03

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Sep 2020 16:16:03



**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Sep 2020 16:16:03

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stone - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 15:55:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 15:55:37
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 15:54:06
User entered 'Left kidney stone exacerbation'	Mariete Rendon (b) (4)	14 Oct 2020 15:53:53
	(b) (4)	

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '7 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:32:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:53:53



US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
Signature has been broken.	Jessie Downs (b) (4)	30 Mar 2021 13:03:37
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	30 Mar 2021 13:03:37
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	14 Oct 2020 15:53:53
	(b) (4)	

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Signature has been broken.	Jessie Downs (b) (4)	30 Mar 2021 13:03:37
	(b) (4)	
User entered '23 Oct 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	30 Mar 2021 13:03:37
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	14 Oct 2020 15:53:53
	(b) (4)	

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:32:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53



**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53



US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'None (NONE)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

None

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	14 Oct 2020 18:26:43
User entered '1' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 18:26:43
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	14 Oct 2020 15:53:53
User entered '0'	Mariete Rendon (b) (4)	14 Oct 2020 15:53:53
	(b) (4)	

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

[Outcome](#)

Audit	User	Time (GMT)
Signature has been broken.	Jessie Downs (b) (4)	30 Mar 2021 13:03:37
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Jessie Downs (b) (4)	30 Mar 2021 13:03:37
Data Entry Error	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Mariete Rendon (b) (4)	14 Oct 2020 15:53:53
	(b) (4)	

US3172211

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53



**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:53:53

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 15:53:53

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 15:53:53

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:32:11**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:22:31
User entered 'USA-US118-2021-mRNA-1273-P301000015'	System	13 Apr 2021 18:22:18
User entered 'New'	(b) (4), (b) (6)	13 Apr 2021 18:22:18

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 16:23:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 16:23:29
Data point term sent to Coder	System	12 Apr 2021 19:13:16
User entered 'worsening back muscle spasm'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21



US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Apr 2021'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:32:11**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:32:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:12:21

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:15:33
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:32:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21



US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:14:38
User entered '10 Apr 2021'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Apr 2021'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

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Folder: Adverse Events

Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'PV QUERY: As the subject received last dose of study drug on 22 Mar 2021 (before the start of SAE), therefore kindly update the action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:15:04
User entered 'None (NONE)'	Jessie Downs (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

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[None](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21



US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:15:55
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

US3172211

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Narrative](#)

Audit	User	Time (GMT)
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)	22 Apr 2021 12:16:03
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:15:44
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)	22 Apr 2021 12:15:15
User entered 'SUBJECT WITH HISTORY OF BACK MUSCLE SPASM SINCE 2018 WITH NO SYMPTOMS UNTIL 10APR2021 WHEN HE STARTED WITH THE PAIN. HE WENT TO DOCTOR HOSPITAL ON THIS DAY MENTIONED AT 5:00 AM ER FOR BETTER EVALUATION AND TREATMENT. HE WAS ADMITTED AT ER FROM 5:00 AM UNTIL 11APR2021 14:00, WHERE HE WAS DISCHARGED HOME WITH TREATMENT. TODAY HE IS HERE ONSITE FOR VISIT DAY 57 AND 209 AS PER PROTOCOL. SUBJECT REPORTED FEELING BETTER BUT CONTINUED WITH TREATMENT. NO OTHER COMPLAINT REPORTED. WE REQUESTED MEDICAL RECORDS AND WILL CONTINUE MONITORING SUBJECT BY PHONE CALL UNTIL MEDICAL RECORDS ARE RECEIVED. SARS-COV-2 (COVID-19) 10APR2021 Results-negative. 10APR32021 Lumbar spine CT Interp Recon impression: 1. posterior instrumented fusion L5-S1. 2. Mild degenartive changes at L4-L5. 3. No acute fracture or dislocation. 4. IVC filter. few of the limbs of the filter are outside of the confines of the IVC lumen. Nonemergent evaluation by interventional radiology is recommended. 10APR2021 abd pel CT wo IV wo PO CON impression: Postsurgical changes, but no acute findings in the abdomen or pelvis.' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 18:55:31

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject with history of back muscle spasm since 2018 with no symptoms until 10Apr2021 when he started with the pain. He went to doctor hospital on this day mentioned at 5:00 am ER for better evaluation and treatment. He was admitted at ER from 5:00 am until 11Apr2021 14:00, where he was discharged home with treatment. Today he is here onsite for visit Day 57 and 209 as per protocol. Subject reported feeling better but continued with treatment. no other complaint reported. We requested medical records and will continue monitoring subject by phone call until medical records are received.'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:12:21

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:12:21

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:12:21

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 19:12:21



US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 15:33:28
User entered 'USA-US118-2021-mRNA-1273-P301000015' reason for change: Obvious Correction	(b) (4), (b) (6)	16 Apr 2021 18:27:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 18:24:23
User entered 'USA-US118-2021-mRNA-1273-P301000017'	System	16 Apr 2021 18:15:51
User entered 'New'	(b) (4), (b) (6)	16 Apr 2021 18:15:51

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 07:45:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 07:45:28
Data point term sent to Coder	System	15 Apr 2021 19:10:19
User entered 'acute exacerbation of abdominal pain'	Jessie Downs (b) (4)	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Apr 2021'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:09:57



**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:19:55
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57



**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Apr 2021'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Apr 2021'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57



US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'PV QUERY: As the subject received last dose of study drug on 22 Mar 2021 (before the start of SAE), therefore kindly update the action taken from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:19:22
User entered 'None (NONE)'	Jessie Downs (b) (4)	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:19:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4)	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57



US3172211

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:32:11

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Date in case narrative for the Lumbar spine CT is reported as 10APR32021. Please correct date format.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:12:45
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)	22 Apr 2021 12:20:03
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:19:36
User opened query 'PV QUERY: Please add medical history of chronic gastritis, as mentioned in the narrative section of the CRF.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 12:19:31
User entered 'AFTER MEDICAL RECORDS RECEIVED AND REVIEWED A NEW SAE WORSENERD AND WILL BE REPORTED TO THE SPONSOR. THIS SAE IS MOST LIKELY RELATED TO PAST MEDICAL HISTORY OF CHRONIC GASTRITIS. SUBJECT WAS ADMITTED AND TREATMENT AT DOCTOR/HOSPITAL FROM 10APR2021 AND DISCHARGED ON 11APR2021. MEDICAL HISTORY AND MEDICATION LOG WERE UPDATED.SARS-COV-2 (COVID-19) 10APR2021 RESULTS- NEGATIVE. 10APR32021 LUMBAR SPINE CT INTERP RECON IMPRESSION: 1. POSTERIOR INSTRUMENTED FUSION L5-S1. 2. MILD DEGENARTIVE CHANGES AT L4-L5. 3. NO ACUTE FRACTURE OR DISLOCATION. 4. IVC FILTER. FEW OF THE LIMBS OF THE FILTER ARE OUTSIDE OF THE CONFINES OF THE IVC LUMEN. NONEMERGENT EVALUATION BY INTERVENTIONAL RADIOLOGY IS RECOMMENDED. 10APR2021 ABD PEL CT WO IV WO PO CON IMPRESSION: POSTSURGICAL CHANGES, BUT NO ACUTE FINDINGS IN THE ABDOMEN OR PELVIS.'	Mariete Rendon (b) (4)	21 Apr 2021 18:59:24
reason for change: Data Entry Error	(b) (4)	

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Narrative](#)

Audit	User	Time (GMT)
User entered 'after medical records received and reviewed a new SAE worsened and will be reported to the sponsor. This SAE is most likely related to past medical history of chronic gastritis. subject was admitted and treatment at doctor/hospital from 10APR2021 and discharged on 11APR2021. medical history and medication log were updated.'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 19:09:57

**US3172211**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 19:09:57

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:32:11

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:07
User closed query 'Per ETRTR: According to SAE page "Worsening Back Muscle Spasm", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 15:18:04
Query 'Per ETRTR: According to SAE page "Worsening Back Muscle Spasm", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' answered with 'Conmed updated' (Site from CRA).	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:10:52
User opened query 'Per ETRTR: According to SAE page "Worsening Back Muscle Spasm", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 23:05:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:12

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
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) (b) (4)	19 Aug 2020 18:46:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:46:26
Data point term sent to Coder	System	19 Aug 2020 18:45:35
User entered 'OMEPRAZOLE'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'HEARTBURN'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '20'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:32:11**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:03:21
User entered 'as needed (PRN)' reason for change: New Information	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:03:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:32:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:32:11**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:03:21
User entered 'UN UNK 2016' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:03:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:35:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 18:44:47
User entered 'UN Feb 2020'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:03:21
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:03:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:03:21
User entered 'un UNK 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:03:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 18:44:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User entered empty.	System	21 Apr 2021 19:03:21
User entered '1'	System	19 Aug 2020 18:44:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User entered empty.	System	21 Apr 2021 19:03:21
User entered '1'	System	19 Aug 2020 18:44:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:30
User entered empty.	System	21 Apr 2021 19:03:21
User entered '804 (804)'	System	19 Aug 2020 18:44:47



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:28:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:28:51
Data point term sent to Coder	System	21 Apr 2021 19:11:29
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:11:03
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 23:03:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 23:03:39
Data point term sent to Coder	System	29 Sep 2020 21:51:41
User entered 'excedrin (Acetaminophen 250mg, aspirin 250mg, caffeine 65mg)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:51:13

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:13
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	21 Apr 2021 19:11:03
	(b) (4)	
User entered 'HEADACHE (secondary to influenza B Infection)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Apr 2021 19:11:03
	(b) (4)	
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 10:22:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'Subject took medication due to Influenza infection (AE was recorded). ' (Site from DM).	Jessie Downs (b) (4)	28 Jan 2021 21:21:05
	(b) (4)	
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 16:47:14
User entered 'headache'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:13
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '250/250/65'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:13
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'mg (mg)'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:13
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	29 Sep 2020 21:51:13
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'once daily (QD)'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:13
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	29 Sep 2020 21:51:13
	(b) (4)	



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:13
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	29 Sep 2020 21:51:13
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '25 Sep 2020'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:13
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:13
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User closed query 'Per CDM : There is an End date noted on the AE log. Please review and update this field accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 03:26:20
Query 'Per CDM : There is an End date noted on the AE log. Please review and update this field accordingly.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	13 Nov 2020 16:49:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	13 Nov 2020 16:47:20
	(b) (4)	
User opened query 'Per CDM : There is an End date noted on the AE log. Please review and update this field accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 12:08:45
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:13
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '25 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	13 Nov 2020 16:47:20
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	29 Sep 2020 21:51:13
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 03:57:44
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	16 Dec 2020 14:22:17
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Dec 2020 14:22:00
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:18:44
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 12:05:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'Consistent with Influenza B infection. Not a seperate AE. ' (Site from DM).	Jessie Downs (b) (4)	06 Nov 2020 14:37:29
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:18:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 15:39:45
User entered 'No (N)'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:13



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User entered '1'	System	29 Sep 2020 21:51:13

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User entered '1'	System	29 Sep 2020 21:51:13

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:17
User entered '804 (804)'	System	29 Sep 2020 21:51:13

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 14:35:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 14:35:22
	(b) (4)	
Data point term sent to Coder	System	06 Nov 2020 14:34:41
Coding entries removed.	Jessie Downs (b) (4)	06 Nov 2020 14:34:23
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 21:53:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 21:53:36
	(b) (4)	
Data point term sent to Coder	System	29 Sep 2020 21:52:42
User entered 'acetaminophen'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MYALGIA, ARTHRALGIA, HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MYALGIA, ARTHRALGIA, HEADACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 12:10:29
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MYALGIA, ARTHRALGIA, HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MYALGIA, ARTHRALGIA, HEADACHES did not meet the AE reporting criteria.' answered with 'No SAR or MAAE. They are part of Influenza B infection.' (Site from DM).	Jessie Downs (b) (4)	06 Nov 2020 14:36:06
User entered 'MYALGIA, ARTHRALGIA, HEADACHES - (No SAR or MAAE)' reason for change: Data Entry Error	Jessie Downs (b) (4)	06 Nov 2020 14:34:23

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MYALGIA, ARTHRALGIA, HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MYALGIA, ARTHRALGIA, HEADACHES did not meet the AE reporting criteria.' (Site from DM). User entered 'myalgia, arthralgia, headaches'	(b) (4), (b) (6)	05 Nov 2020 13:19:09
	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '1000'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59
	(b) (4)	



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'mg (mg)'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'once daily (QD)'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '25 Sep 2020'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59
	(b) (4)	



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 15:38:49
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '28 Sep 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 15:38:49
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 03:58:01
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	16 Dec 2020 14:23:07
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Dec 2020 14:22:50
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:18:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 15:39:03
User entered 'No (N)'	Mariete Rendon (b) (4)	29 Sep 2020 21:51:59

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User entered '1'	System	29 Sep 2020 21:51:59

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User entered '1'	System	29 Sep 2020 21:51:59

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:26
User entered '804 (804)'	System	29 Sep 2020 21:51:59

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
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)	29 Sep 2020 23:59:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Sep 2020 23:59:50
	(b) (4)	
Data point term sent to Coder	System	29 Sep 2020 21:53:44
User entered 'tramadol'	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'arthralgia (rib cage)'	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '50'	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'mg (mg)'	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'once (ONCE)'	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '28 Sep 2020'	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '28 Sep 2020'	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 15:40:10
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	29 Sep 2020 21:52:49
	(b) (4)	

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User entered empty.	System	29 Sep 2020 21:52:49

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User entered empty.	System	29 Sep 2020 21:52:49

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:55:27
User entered empty.	System	29 Sep 2020 21:52:49



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 06:22:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 06:22:41
	(b) (4)	
Data point term sent to Coder	System	29 Sep 2020 21:53:45
User entered 'vitamin c over the counter'	Mariete Rendon (b) (4)	29 Sep 2020 21:53:37
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:53:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'fatigue'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:53:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '1000'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:53:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:53:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:53:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:53:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:53:37



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:53:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:53:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '29 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:53:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:53:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:53:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:53:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FATIGUE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 12:12:02
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FATIGUE did not meet the AE reporting criteria.' answered with 'Not AE. Mild Serious Adverse Reaction.' (Site from DM).	Jessie Downs (b) (4)	06 Nov 2020 20:51:26
	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FATIGUE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:20:02

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:53:37



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 21:53:37

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 21:53:37

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 21:53:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 12:23:18
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Oct 2020 12:23:18
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 23:46:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 23:46:42
	(b) (4)	
Data point term sent to Coder	System	29 Sep 2020 21:54:48
User entered 'vitamin d over the counter'	Mariete Rendon (b) (4)	29 Sep 2020 21:54:37
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:54:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'fatigue'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:54:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '1000'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:54:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:54:37



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:54:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:54:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:54:37

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:54:37

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:54:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '29 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:54:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:11

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:54:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:54:37



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Sep 2020 21:54:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:11

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FATIGUE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 12:11:30
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FATIGUE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FATIGUE did not meet the AE reporting criteria.' answered with 'Not AE. Just a mild Serious Adverse Reaction.' (Site from DM).	Jessie Downs (b) (4)	06 Nov 2020 20:53:06
	(b) (4)	



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 21:54:37

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 21:54:37

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Sep 2020 21:54:37

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 16:20:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 16:20:46
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:20:15
User entered 'acetaminophen'	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'Influenza B'	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '1000'	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'mg (mg)'	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'three times daily (TID)'	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '29 Sep 2020'	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 15:41:02
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '3 Oct 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 15:41:02
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	30 Sep 2020 16:19:14
	(b) (4)	

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User entered '3'	System	30 Sep 2020 16:19:14

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User entered '1'	System	30 Sep 2020 16:19:14

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:20
User entered '804 (804)'	System	30 Sep 2020 16:19:14



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NEURAMINIDASE INHIBITORS, PRODUCT: OSELTAMIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Oct 2020 07:30:33
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Oct 2020 07:30:33
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:20:14
User entered 'oseltamivir'	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'Influenza B'	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '75'	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'mg (mg)'	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'twice daily (BID)'	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '29 Sep 2020'	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 15:41:26
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '3 Oct 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 15:41:26
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	30 Sep 2020 16:20:05
	(b) (4)	

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User entered '2'	System	30 Sep 2020 16:20:05



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User entered '1'	System	30 Sep 2020 16:20:05

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:58:22
User entered '804 (804)'	System	30 Sep 2020 16:20:05

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 18:02:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 18:02:48
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:21:16
User entered 'clonazepam'	Mariete Rendon (b) (4)	30 Sep 2020 16:20:47
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:20:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'schizophrenia'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:20:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '1'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:20:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:20:47

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:32:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:20:47



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:20:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:20:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:20:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:20:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'un UNK 2000'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:20:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:11

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:20:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	21 Apr 2021 19:19:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Apr 2021 19:19:00
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	30 Sep 2020 16:20:47
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	21 Apr 2021 19:19:00
	(b) (4)	
User entered '10 Apr 2021' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Apr 2021 19:19:00
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:20:47
	(b) (4)	



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:20:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 16:20:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 16:20:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 16:20:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 18:02:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 18:02:48
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:28:41
User entered 'clopidogrel'	Mariete Rendon (b) (4)	30 Sep 2020 16:28:31
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:28:31

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:32:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'cardiovascular prophylaxis'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:28:31

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '75'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:28:31



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:28:31

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:32:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:28:31

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:28:31

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:28:31

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:28:31

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:28:31

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'un UNK 2018'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:28:31

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:11

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:28:31



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:28:31

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:28:31

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:28:31

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 16:28:31

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 16:28:31

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 16:28:31

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: METFORMIN HYDROCHLORIDE;SITAGLIPTIN, PRODUCTSYNONYM: JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 16:31:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 16:31:48
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:30:45
User entered 'janumet'	Mariete Rendon (b) (4)	30 Sep 2020 16:29:47
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:29:47



US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:32:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'diabetes mellitus type 2'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:29:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '50/500'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:29:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:29:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:29:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'twice daily (BID)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:29:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:29:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:29:47

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:29:47



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'un UNK 2018'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:29:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:11

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:29:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:29:47

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:29:47

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:29:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Sep 2020 16:29:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 16:29:47

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 16:29:47



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL DOSEPAK - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 07:27:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL [METHYLPREDNISOLONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Oct 2020 08:12:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:31:47
User entered 'medrol dose pack'	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'Influenza B'	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '4'	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'mg (mg)'	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'other (OTHER)'	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'as directed times 5 days'	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '29 Sep 2020'	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 15:47:51
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered '3 Oct 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	14 Oct 2020 15:47:51
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	30 Sep 2020 16:31:20
	(b) (4)	

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User entered empty.	System	30 Sep 2020 16:31:20



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User entered empty.	System	30 Sep 2020 16:31:20

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:32:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:56:58
User entered empty.	System	30 Sep 2020 16:31:20

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: RISPERIDONE, PRODUCTSYNONYM: RIPERIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 16:33:55
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 16:33:55
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:32:49
User entered 'riperidone'	Mariete Rendon (b) (4)	30 Sep 2020 16:32:03
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:03

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'schizophrenia'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:03

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '3'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:03

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:03

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:03



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'twice daily (BID)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:03

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:32:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:03

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:03

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:03

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'un UNK 2005'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:03

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:03

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	21 Apr 2021 19:21:20
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Apr 2021 19:21:20
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	30 Sep 2020 16:32:03
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Signature has been broken.	Mariete Rendon (b) (4)	21 Apr 2021 19:21:20
	(b) (4)	
User entered '10 Apr 2021' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Apr 2021 19:21:20
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	30 Sep 2020 16:32:03
	(b) (4)	



US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:03

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Sep 2020 16:32:03

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 16:32:03

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 16:32:03

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: TEMAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 16:33:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 16:33:57
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 16:32:49
User entered 'temazepam'	Mariete Rendon (b) (4)	30 Sep 2020 16:32:30
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'insomnia'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '30'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:30



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:30

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:32:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'as needed (PRN)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'un UNK 2010'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:11

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:30



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:30

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:32:30

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:32:30

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:32:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:32:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:35:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 16:35:01
Data point term sent to Coder	System	30 Sep 2020 16:33:50
User entered 'famotidine'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:32:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:32:11**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'heartburn'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:32:11**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '20'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'twice daily (BID)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:32:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'un UNK 2019'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:48:54
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'un Mar 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:48:54
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 16:32:57

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User entered '2'	System	30 Sep 2020 16:32:57

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User entered '1'	System	30 Sep 2020 16:32:57

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:37
User entered '804 (804)'	System	30 Sep 2020 16:32:57



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:08:30
	(b) (4)	
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: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 15:50:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 15:50:49
Data point term sent to Coder	System	14 Oct 2020 15:49:59
User entered 'pantoprazole'	Mariete Rendon (b) (4)	14 Oct 2020 15:49:45
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:49:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'heartburn'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:49:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '40'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:49:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:49:45

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:32:11**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:49:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:49:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:49:45



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:49:45

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:49:45

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'un Apr 2020'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:49:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered '0'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:49:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:49:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:49:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 15:49:45

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 15:49:45



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 15:49:45

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 15:49:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
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)	12 Apr 2021 20:38:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 20:38:36
	(b) (4)	
Data point term sent to Coder	System	12 Apr 2021 19:17:23
User entered 'metoprolol'	Jessie Downs (b) (4)	12 Apr 2021 19:16:29
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:16:29

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'hypertension'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:16:29

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '25'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:16:29

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:16:29

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:16:29



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:16:29

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:16:29

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:16:29

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:16:29

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'un UNK 2018'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:16:29

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:16:29

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:16:29

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:16:29



US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 19:16:29

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:16:29

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 19:16:29

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 19:16:29

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:32:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 00:36:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 00:36:42
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 19:26:43
Coding entries removed.	Mariete Rendon (b) (4)	21 Apr 2021 19:25:48
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 09:22:02
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 09:22:02
	(b) (4)	
Data point term sent to Coder	System	15 Apr 2021 19:12:20
User entered 'methocarbamol'	Jessie Downs (b) (4)	15 Apr 2021 19:11:58
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:11:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Worsening Chronic Lower back pain' reason for change: New Information	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:25:48
User entered 'muscle relaxants'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:11:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '750'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:11:58



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg (mg)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:25:48
User entered 'mL (mL)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:11:58

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:32:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:11:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'three times daily (TID)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:11:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:32:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:11:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:11:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:11:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '11 Apr 2021'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:11:58

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:11:58



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:32:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:11:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:11:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	15 Apr 2021 19:11:58

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Apr 2021 19:11:58

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 19:11:58

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 19:11:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, PRODUCT: AMANTADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:01:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:01:50
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 19:29:53
User entered 'Amantadine'	Mariete Rendon (b) (4)	21 Apr 2021 19:29:01
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:01



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Antiviral Influenza preventive'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:01

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:32:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '100'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:01

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:01

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:01

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:01

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:01

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:01

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:01



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'un UNK 2020'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:01

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:01

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:01

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:32:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:01

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:01

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:29:01

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:29:01

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 19:29:01



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:04:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:04:02
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 19:30:58
User entered 'Clonazepam'	Mariete Rendon (b) (4)	21 Apr 2021 19:29:58
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Anxiety'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '1'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'twice daily (BID)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:58



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:58

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '10 Apr 2021'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:32:11

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:29:58

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 19:29:58



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:29:58

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 19:29:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
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)	22 Apr 2021 05:22:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:22:47
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 19:32:00
User entered 'donepezil'	Mariete Rendon (b) (4)	21 Apr 2021 19:31:33
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:31:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Mild Memory Loss'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:31:33

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:32:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '5'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:31:33

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:32:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:31:33

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:32:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:31:33



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:31:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:31:33

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:31:33

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:31:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'un UNK 2019'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:31:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:31:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:31:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:31:33



US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:31:33

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:31:33

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:31:33

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 19:31:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: RISPERIDONE, PRODUCTSYNONYM: RISPERDAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:04:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:04:06
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 19:33:01
User entered 'Risperdal'	Mariete Rendon (b) (4)	21 Apr 2021 19:32:32
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:32:32

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'schizophrenia'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:32:32

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '2'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:32:32



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:32:32

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:32:11**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:32:32

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'twice daily (BID)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:32:32

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:32:32

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:32:32

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:32:32

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '10 Apr 2021'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:32:32

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:32:32



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:32:32

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:32:32

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:32:32

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 19:32:32

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:32:32

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 19:32:32

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:04:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:04:11
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 19:34:01
User entered 'Gabapentin'	Mariete Rendon (b) (4)	21 Apr 2021 19:33:45
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:33:45



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Diabetes Neuropathy'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:33:45

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:32:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '300'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:33:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:33:45

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:32:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:33:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'three times daily (TID)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:33:45

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:32:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:33:45

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:33:45

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:33:45



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'un UNK 2018'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:33:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:33:45

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:32:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:33:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:33:45

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:33:45

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 19:33:45

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:33:45

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 19:33:45



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:04:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:04:11
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 19:35:02
User entered 'Acetaminophen'	Mariete Rendon (b) (4)	21 Apr 2021 19:34:43
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:34:43

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:32:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Worsening chronic Lower Back pain'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:34:43

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:32:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '650'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:34:43

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:34:43

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:32:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:34:43

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'as needed (PRN)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:34:43

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:32:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:34:43



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:34:43

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:34:43

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '10 Apr 2021'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:34:43

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:34:43

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:34:43

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:34:43

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:34:43

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:34:43



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:34:43

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:34:43

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
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)	22 Apr 2021 05:20:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:20:43
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 19:36:03
User entered 'divalproex'	Mariete Rendon (b) (4)	21 Apr 2021 19:36:02
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:36:02

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'schizophrenia'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:36:02

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '250'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:36:02

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:36:02

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:36:02



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'three times daily (TID)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:36:02

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:36:02

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:36:02

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:36:02

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '10 Apr 2021'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:36:02

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:36:02

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:36:02

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:36:02



US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:36:02

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	21 Apr 2021 19:36:02

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:36:02

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 19:36:02

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:04:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:04:20
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 19:38:05
User entered 'Adderall XR'	Mariete Rendon (b) (4)	21 Apr 2021 19:37:20
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:37:20

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:32:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Attention deficit hyperactive disorder'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:37:20

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:32:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '20'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:37:20



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:37:20

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:37:20

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:37:20

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:37:20

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:37:20

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:37:20

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'un UNK 2010'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:37:20

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:37:20



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:37:20

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:37:20

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:37:20

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:37:20

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:37:20

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 19:37:20

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
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: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: SUCRALFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:05:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:05:25
Data point term sent to Coder	System	21 Apr 2021 19:46:12
User entered 'sucralfate'	Mariete Rendon (b) (4)	21 Apr 2021 19:45:41
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:45:41



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Gastroesophageal reflux disease'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:45:41

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '1'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:45:41

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'g (g)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:45:41

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:45:41

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:45:41

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:45:41

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:45:41

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:45:41



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '10 Apr 2021'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:45:41

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:45:41

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:45:41

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:45:41

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:45:41

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:45:41

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:45:41

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 19:45:41



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:31:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:31:42
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 19:54:20
User entered 'Albuterol 2.5mg'	Mariete Rendon (b) (4)	21 Apr 2021 19:53:21
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:53:21

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Chronic obstructive pulmonary disease'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:53:21

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '1.25/3'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:53:21

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mL (mL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:53:21

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:53:21

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'as needed (PRN)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:53:21

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:53:21



US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:53:21

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:53:21

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'un UNK 1980'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:53:21

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:53:21

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:53:21

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:32:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:53:21

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:53:21

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:53:21



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:53:21

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:53:21

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:32:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: ARFORMOTEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:44:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:44:50
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 19:55:23
User entered 'arformoterol'	Mariete Rendon (b) (4)	21 Apr 2021 19:54:51
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:54:51

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Chronic obstructive pulmonary disease'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:54:51

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '15'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:54:51

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:32:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'ug (ug)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:54:51

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:54:51



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'twice daily (BID)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:54:51

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:32:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:54:51

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:54:51

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:54:51

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'un UNK 1980'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:54:51

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:54:51

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:54:51

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:54:51



US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:54:51

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 19:54:51

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:54:51

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 19:54:51

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:32:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BUDESONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:15:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:15:53
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 19:57:25
User entered 'Budesonide 0.5mg'	Mariete Rendon (b) (4)	21 Apr 2021 19:56:30
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:56:30

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:32:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Chronic obstructive pulmonary disease'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:56:30

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:32:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0.5/2'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:56:30



US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:32:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Other (OTHER)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:56:30

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:32:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg/ml'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:56:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'twice daily (BID)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:56:30

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:32:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:56:30

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:56:30

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:56:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'un UNK 1980'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:56:30

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:56:30



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:56:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:56:30

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:56:30

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 19:56:30

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:56:30

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 19:56:30

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:19:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:19:41
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 19:58:26
User entered 'Diclofenac'	Mariete Rendon (b) (4)	21 Apr 2021 19:57:38
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:57:38



US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:32:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Worsening chronic lower back pain'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:57:38

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '75'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:57:38

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:57:38

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:32:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:57:38

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'twice daily (BID)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:57:38

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:32:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:57:38

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:57:38

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:57:38



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '10 Apr 2021'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:57:38

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:57:38

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:57:38

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:57:38

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:57:38

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 19:57:38

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:57:38

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 19:57:38



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:06:04
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	21 Apr 2021 20:06:04
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 19:59:26
User entered 'Hydralazine'	Mariete Rendon (b) (4)	21 Apr 2021 19:59:18
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:59:18

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Hypertension'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:59:18

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '10'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:59:18

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:59:18

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:32:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:59:18

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'as needed (PRN)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:59:18

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:32:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:59:18



US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:59:18

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:59:18

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '10 Apr 2021'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:59:18

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:59:18

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Apr 2021 19:59:39
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	21 Apr 2021 19:59:18
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User entered '11 Apr 2021' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Apr 2021 19:59:39
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	21 Apr 2021 19:59:18
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 19:59:18

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:59:18



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:59:18

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 19:59:18

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 06:15:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 06:15:45
	(b) (4)	
Data point term sent to Coder	System	21 Apr 2021 20:01:29
User entered 'Zofran'	Mariete Rendon (b) (4)	21 Apr 2021 20:00:33
	(b) (4)	

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:00:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Gastroesophageal reflux disease'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:00:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '4'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:00:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:00:33

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:32:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:00:33



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'as needed (PRN)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:00:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:00:33

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Intravenous (INTRAVENOUS)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:00:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:00:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '10 Apr 2021'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:00:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:32:11

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:00:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:00:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '11 Apr 2021'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:00:33



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:00:33

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 20:00:33

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 20:00:33

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 20:00:33

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: ERGOCALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:25:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:25:49
Data point term sent to Coder	System	21 Apr 2021 20:02:38
User entered 'ergocalciferol'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Vitamin Deficiency'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '50000'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'IU (IU)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:32:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'every week (QS)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:32:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:32:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:32:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '12 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:01:58

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 20:01:58

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 20:01:58

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	21 Apr 2021 20:01:58

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 20:06:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 20:06:15
Data point term sent to Coder	System	21 Apr 2021 20:04:41
User entered 'Glimepiride'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'diabetes type 2'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '4'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:32:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'twice daily (BID)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:32:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:32:11**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'un UNK 2018'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:32:11

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:32:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:32:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:04:11

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 20:04:11

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 20:04:11

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 20:04:11



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:32:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 07:17:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 07:17:54
Data point term sent to Coder	System	21 Apr 2021 20:06:54
User entered 'Symbicort (Puff)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Chronic obstructive pulmonary disease'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '160/45'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'ug (ug)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:32:11**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'twice daily (BID)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:32:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:32:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'un UNK 1980'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:32:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:32:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:32:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:06:14

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 20:06:14



**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 20:06:14

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 20:06:14

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:32:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:42:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:42:51
Data point term sent to Coder	System	21 Apr 2021 20:09:58
User entered 'Humalog sliding scale- 20-130- 0 units, 131-180- 2 units, 181-240- 4 units, 241-300- 6 units, 301-350- 8 units, 351-400- 10 units, >400-12 units'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:32:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:32:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Diabetes type 2'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:32:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '1000'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:32:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Other (OTHER)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:32:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'units/ml'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:32:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'twice daily (BID)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:32:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:32:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Subcutaneous (SUBCUTANEOUS)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56

US3172211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:32:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:32:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '10 Apr 2021'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:32:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:32:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56

US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:32:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '11 Apr 2021'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56



US3172211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:32:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 20:09:56

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:32:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Apr 2021 20:09:56

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 20:09:56

**US3172211**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 15:32:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 20:09:56

US3172211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:32:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 18:29:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 18:29:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:08:30
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 17:11:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 17:11:25

US3172211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:32:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '10 Apr 2021'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 18:57:33

US3172211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:32:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'ABD PEL CT wo IV wo PO CON'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 18:57:33

US3172211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 18:57:33



US3172211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:32:11

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 18:57:33

US3172211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:32:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered '10 Apr 2021'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 18:58:20

US3172211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:32:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Lumbar spine CT Interp Recon'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 18:58:20

US3172211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:32:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 18:58:20

US3172211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:32:11

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Apr 2021 18:58:20

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered		
'USA-US118-2021-MRNA-1273-P301000015'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Yes (Y)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18



**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Yes (Y)'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Mark'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Kutner'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'FL'	System	13 Apr 2021 18:22:18



US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 15:34:37
User entered 'US'	System	13 Apr 2021 18:23:20

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 15:35:06
User entered '2'	System	16 Apr 2021 18:28:18
User entered '1'	System	13 Apr 2021 18:23:20

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered		
'USA-US118-2021-MRNA-1273-P301000015'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Yes (Y)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Yes (Y)'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18



**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Mark'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Kutner'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'FL'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 15:34:37
User entered 'US'	System	13 Apr 2021 18:23:20

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 15:35:06
User entered '2'	System	16 Apr 2021 18:28:18
User entered '1'	System	13 Apr 2021 18:23:20

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User entered '13/Apr/2021 18:23'	System	13 Apr 2021 18:23:20



US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:32:11

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 15:34:37
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 18:23:20

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'USA-US118-2021-MRNA-1273-P301000015'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Yes (Y)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Yes (Y)'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18



US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Mark'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Kutner'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'FL'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 15:34:37
User entered 'US'	System	13 Apr 2021 18:23:20

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 15:35:06
User entered '2'	System	16 Apr 2021 18:28:18
User entered '1'	System	13 Apr 2021 18:23:20

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:32:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User entered '16/Apr/2021 14:28'	System	16 Apr 2021 18:28:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:32:11

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 15:34:37
User entered 'I'	(b) (4), (b) (6)	16 Apr 2021 18:28:18



**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered		
'USA-US118-2021-MRNA-1273-P301000015'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Yes (Y)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Yes (Y)'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'No (N)'	System	13 Apr 2021 18:22:18



US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Mark'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'Kutner'	System	13 Apr 2021 18:22:18

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 18:23:12
User entered 'FL'	System	13 Apr 2021 18:22:18

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Apr 2021 15:34:37
User entered 'US'	System	13 Apr 2021 18:23:20

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 15:35:06
User entered '2'	System	16 Apr 2021 18:28:18
User entered '1'	System	13 Apr 2021 18:23:20

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000015**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:32:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User entered '22/Apr/2021 11:35'	System	22 Apr 2021 15:35:06

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:32:11

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
User entered 'I'	(b) (4), (b) (6)  (b) (4), (b) (6)	22 Apr 2021 15:35:06

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered		
'USA-US118-2021-MRNA-1273-P301000017'	System	16 Apr 2021 18:15:51



**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'Yes (Y)'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'No (N)'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'No (N)'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'Yes (Y)'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'No (N)'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'No (N)'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'No (N)'	System	16 Apr 2021 18:15:51

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'Mark'	System	16 Apr 2021 18:15:51



US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'Kutner'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'FL'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'US'	System	16 Apr 2021 18:16:17

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 18:16:17

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered		
'USA-US118-2021-MRNA-1273-P301000017'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'Yes (Y)'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'No (N)'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'No (N)'	System	16 Apr 2021 18:15:51



**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'Yes (Y)'	System	16 Apr 2021 18:15:51

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'No (N)'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'No (N)'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'No (N)'	System	16 Apr 2021 18:15:51

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'Mark'	System	16 Apr 2021 18:15:51

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'Kutner'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'FL'	System	16 Apr 2021 18:15:51

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'US'	System	16 Apr 2021 18:16:17



**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:32:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 18:16:17

**US3172211**

**Folder: SAE USA-US118-2021-MRNA-1273-P301000017**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:32:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:05
	(b) (4)	
User entered '16/Apr/2021 14:16'	System	16 Apr 2021 18:16:17

US3172211

Folder: SAE USA-US118-2021-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:32:11

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:05
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 18:16:21
User entered 'I'	(b) (4), (b) (6)	16 Apr 2021 18:16:17